A STUDY ON
THANDAGAVATHAM
(Lumbar spondylosis)

Dissertation Submitted To

THE TAMIL NADU Dr. M.G.R. Medical University

Chennai – 32

For the Partial fulfillment for the Award of Degree of

DOCTOR OF MEDICINE (SIDDHA)

(Branch – III, SIRAPPU MARUTHUVAM)

DEPARTMENT OF SIRAPPU MARUTHUVAM

Government Siddha Medical College

Palayamkottai – 627 002.

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PALAYAMKOTTAI, TIRUNELVELI-627002,
TAMILNADU, INDIA.

Phone: 0462-2572736 / 2572737/ Fax:0462-2582010
Email: gsmc.palayamkottai@gmail.com

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This is to certify that the dissertation entitled **"A STUDY ON THANDAGAVATHAM** is a bonafide work done by **DR. M. MALARVIZHI, (Reg No: 321513005) GOVERNMENT SIDDHA MEDICAL COLLEGE, PALAYAMKOTTAI** in partial fulfillment of the University rules and regulations for award of **M.D (SIDDHA), BRANCH - III SIRAPPU MARUTHUVAM** under my guidance and supervision during the academic year **2015-2018 OCTOBER.**

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TAMILNADU, INDIA.

Phone: 0462-2572736 / 2572737/ Fax:0462-2582010
Email: gsmc.palayamkottai@gmail.com

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I hereby declare that this dissertation entitled **"A STUDY ON THANDAGAVATHAM"** is a bonafide and genuine research work carried out by me under the guidance of **Prof. Dr. A. S. POONGODI KANTHIMATHI., M.D(s).,** HOD, PG - Department of Sirappu Maruthuvam, Govt. Siddha Medical College, Palayamkottai and the dissertation has formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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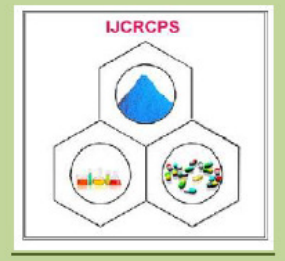

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[2]PG Scholar, Dept. of Sirappu Maruthuvam, Government Siddha Medical College, Palayamkottai, Tirunelveli – 627002.

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[2]PG Scholar, Dept. of Sirappu Maruthuvam, Government Siddha Medical College, Palayamkottai, Tirunelveli – 627002.
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Email ID : gsmc.palayamkottai@gmail.com

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Principal investigator	Dr.M.Malarvizhi. I Year, PG Dept Sirappu Maruthuvam Reg.No :
Guide	Dr.A.S.Poongodi kanthimathi. M.D (s) Professor &Head of the Department
Dissertation topic	An open clinical Study to evaluate the clinical efficacy of siddha sasthric formulation "**KUSTATHI CHOORNAM**"(Internal) "**ERANDA THYLAM**"for the treatment of **THANDAGA VATHAM.**
Document field	1. Protocol2. Date Collection Form 3. Patient Information Sheet 4. Consent form5. SAE (Pharmacovigilance)
Clinical / Non Clinical trial Protocol	Clinical trial protocol – Yes
Informed consent document	Yes
Any other document	Case sheet, Investigation document
Date of IEC approval & it's Number	GSMC/3.IEC/2016/III-24/20.07.16

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

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Email id :gsmc.palayamkottai@gmail.com

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified the following plant drugs used in siddha formulation **KUSTATHI CHOORNAM (INTERNAL) & ERANDA THYLAM (EXTERNAL)** for management of **THANDAGA VATHAM (LUMBAR SPONDYLOSIS)** taken up for post-graduation dissertation studies by **Dr. M.MALARVIZHI M.D (S). , (REG.NO:321513005)** PG scholar, department of sirappu maruthuvam are correctly identified and authenticated through Visual inspection / Organoleptic characters / Experience, Education & Training morphology, microscopical and taxonomical methods.

INGREDIENTS OF KUSTATHI CHOORNAM

S.NO	DRUGS	BOTANICAL NAME	FAMILY	PART USED
1	Kostam	Saussurea lappa	Asteraceae	Root
2	Vetpalaivirai	Wrightia tinctoria	Apocynaceae	Seed
3	Chukku	Zingiber officinalae	Zingiberaceae	Rhizome
4	Chitramoolam	Plumbago zeylanica	Plumbaginaceae	Root
5	Athividayam	Cryptocoryne spiralis	Araceae	Root
6	Manjal	Curcuma longa	Zingiberaceae	Rhizome

INGREDIENTS OF ERANDA THYLAM

s.no	drugs	Botanical name	family	Part used
1.	Milagu	Piper longum	Piperaceae	Unriped fruit
2.	Manjal	Curcuma longa	Zingiberaceae	Rhizome
3.	Vellai Poondu	Allium sativum	Liliaceae	Bulb
4.	Kuppaimeni Saru	Acalypha indica	Euphorbiaceae	Whole plant
5.	Kadugu	Brassica juncea	Brassicaceae	Seed

Station:

Date:

Authorized signature

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai, Tirunelveli - 2.

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Dr. A. Rajasekaran
Biological Scientist and IAEC Chairperson

PRINCIPAL
KMCH College of Pharmacy,
Kovai Estate, Kalapatti Road,
Coimbatore - 641 048.
Tamil Nadu, INDIA

KMCH College of Pharmacy ★ Coimbatore - 641 035

17/12/18

Dr. D. Kannan
Main Nominee [CPCSEA]

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for the Participation and Implementation of **"International Day of Yoga"**

held on 21-06-2018 at Government Siddha Medical College & Hospital, Palayamkottai.

International Day of Yoga 21 June

Yoga for Harmony & Peace

Prof.**Dr. A.S. Poongodi Kanthimathi** M.D (Siddha).,
Head - Department of Sirappu Maruthuvam.

Prof. **Dr. R.Neelavathy** M.D (Siddha)., Ph.D.,
Prinicipal.

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INTRODUCTION

The word ***"Siddha"*** comes from the word ***"siddhi"***, which means an object to attain perfection or heavenly bliss. Siddha generally refers to Attama siddhi that is the 8 super natural powers those who attained or achieved the above said powers are know as ***"Siddhars"***.Siddhars were saintly figures. There were eighteen important siddhars in olden days and they developed this medicine.

Origin :

The origin of siddha system of medicine, traces back to the submerged Lemurian continent. Its was conceived and crafted by the ancient siddhars who's principle Language was Tamil. The origin of the system and the usaged of medicinal plants belongs to the age of the Sangam Literatures as early as 3000 B.C. ***"Tholkappiam"*** and***"Thirumanthiram"*** stands as a proof to this.

Basic principles :

Siddha system of medicine is based on ***"Saiva Siddhantha"*** . The prime principle of saiva siddhantha is to become one with the gods almighty and that is determined as a goal of life. The goal of life can be achieved by keeping the health of our mortal body. The could be known by Thirumoolar in line, which says,

உடம்பார் அழியில் உயிரால் அழிவர்

திடம்பட மெய்ஞானம் சேரவும் மாட்டார்

உடம்பை வளர்க்கும் உபாயம் அறிந்தே

உடம்பை வளர்த்தேன் உயிர் வளர்ந்தேனே !

- திருமந்திரம்

Siddha science considers nature and man as essentially one. Nature is man and man is nature. Man is said to be the microcosm and universe is the macrocosm because what exists in the world exists in man. Man is nothing but a miniature world, containing the five elements of various principles which constitute the minerals plants, and animal kingdom .

According to siddha medical science, the universe originally. Consisted of atoms which contributed to the five basic elements. Viz.,

Prithivi - Earth

Appu - water

Theyu - Fire

Vayu - Air

Agayam - Sky

Among these elements.

- Earth – gives fine shapes to the body includes bones tissue, muscles, skin, hair, etc,
- water – represents for blood secretions of the gland, vital fluid etc.
- Fire – gives motion, vigor and vitality to the body.

These three elements are primarily responsible for the formation of three humours,

- Vatham
- Pitham
- Kabam.

These are the three fundamental functional constituents of human body and these are supposed to be in the proportion of 1: ½ : ¼ in a healthy individual and are known as "Muthathukkal"(முத்தாதுக்கள்).But when this equilibrium is disarranged these are known as mukkutrangal (முக்குற்றங்கள்) which lead to disease. This principle is quoted by ***Thiruvalluvar***as

மிகினும் குறையினும் நோய்செய்யும் நூலோர்

வளிமுதலா எண்ணிய மூன்று

-திருக்குறள்

The Fundamental subjects of Siddha methodology

1.Vadham (Alchemy)

2. Vaithiyam (medicine)

3. yogam (yoga)

4. Gyanam or Thathuvam (philosophy)

Meateria Medica :

The siddha system has three classifications over the sources of the drug. They are

- Mooligai vaguppu – plant sources.
- Thathu Vaguppu – metal and mineral sources
- Jeeva Vaguppu- animal sources.

CHEMISTRY IN SIDDHA SYSTEM:

In siddha system, chemistry had been found well developed into science auxilliary to medicine and alchemy. It was found useful in the preparation of medicine as well as in transmutation of basic metals into gold. The siddhars were aware of several chemical operations divided into several process such as :

- Calcination
- Sublimation
- Distillation
- Fusion
- Separation
- Fermentation
- Exaltation etc.

With the help of these,various medicines are prepared to cure the various diseases.According to the siddha literature,there are 4448 diseases.Among them 80 vadha diseases.

In that, Thandaga vatham is one of the most common degenerative joint disorder causing health problems for backache to neurological problems**. Yugimunivar** has classified**"Thandaga vatham"** as one among the 80 types of vatha disease. The disease Thandaga vatham (**Yugi vaidhiya chinthamani Page No. 109-110)** can be correlated to **Lumbar spondylosis.**Age 45-64 years identified 85.5% of Osteophytes within the lumbar spine.

27-37% of symptomatic population internationally Lumbar spondylosis can begin in person as young as 20 years.

10% of women age 20-29 to have evidence of disc degeneration, lumbar spondylosis while affecting 80% older than 40 years nevertheless was found 3% of individuals aged 20-29 years.

Approximately 84% of men and 74% of women have vertebral osteophytes, most frequently at T9-10 and L3 levels. Approximately 30% of men and 28% of women aged 55-64 years have lumbar osteophytes. Approximately 20% of men and 22% of women aged 45-64 years have lumbar osteophytes.

All of the symptoms may disappear when the patient ceases walking even though he remains in the standing position at times however the symptoms may be exacerbated by prolonged standing and relieved by only sitting or lying down.Sitting for prolonged periods of time may cause pain and other symptoms due to pressure on lumbar vertebrae. Repetitive movements such as lifting and bending (eg: manual labour) may increase pain.

It commonly affects different sects of people like tailors, drivers, clerks, etc. most recent additions are IT sector people.

Treatment is usually conservative in nature; the most commonly used treatments are non-steroidal anti-inflammatory drugs (NSAIDs), analgesics (rarely steroids and opioids), physical modalities, and lifestyle modifications. Surgery is occasionally performed.Hence there is an immense gap between the disease and its management and if an alternative medication is proved, there is much hope, that this gap can be reduced greatly. Hence the author has taken “Thandaga vatham” comparable with lumbar spondylosis as research topic.

Numerous Siddha drugs are available to treat this disease and many of them have been tried already and have shown good results. Yet the author has chosen a new drug, from the classical text. This is because, as lumbar spondylosis is mostly degenerative disease, a special combination with rejuvenating drugs, from a classical textbook of medicine, could give excellent prognosis.

The author's choices of medicines for the clinical study are

INTERNAL DRUG: KUSTATHI CHOORNAM (1 GRAM WITH HOT WATER)

(ANUBOGA VAITHIYA DEVARAGASIYAM)Pg No., 424

EXTERNAL MEDICINE: ERANDA THYLAM (30 ml).

(SARABANTHIRA VAITHIYA MURAIGAL- VATHAROGA CHIKKICHAI)

Pg No., 12

AIM AND OBJECTIVE

AIM :

Phase II criteria based clinical study of **THANDAGAVATHAM** (Lumbar spondylosis) and the drug choice **KUSTATHI CHOORNAM** (internal) and **ERANDA THYLAM** (External)

OBJECTIVE :

Primary objective :

To evaluate the clinical efficacy of **KUSTATHI CHOORNAM (**internal) and **ERANDATHYLAM** (external) for the treatment of **THANDAGA VATHAM** (LUMBAR SPONDYLOSIS).

Secondary objective:

- To study the Siddha basic principles like envagaithervukkal including neerkkuri and neikkuri.
- To evaluate the safety profile of the trial medicine.
- To Evaluate the pharmacological study of trial medicine

REVIEW OF LITERATURE

SIDDHA ASPECTS

தண்டகவாதம்

'யூகி வைத்திய சிந்தாமணி" நூலில் வாத நோய்கள் 80 வகையாக விவரிக்கப்பட்டு உள்ளது. இதில் ஒன்று **தண்டகவாதம்.**

Definition :

அவயவங்களை செயலறச் செய்து உடம்பை தண்டகத்தைப் போல் வீழ்த்தி நீட்டல் மடக்கல், அசைத்தல் முதலியவை இல்லாமல் சவத்தைப் போல் கிடக்கச் செய்யும் வாத நோயாகும்.

A kind of rheumatism chareterised by great prostration in which the body is rendered like a log of wood , unable to stretch of fold the limbs and pass motion or urine. The whole body assumes a thorough rigidity as the stiffness appearing after death.

-T.V.Sambasivapillai agarathi IV.

Etiology:

The etiological factors of thandaga vatham are similar to that of the common etiological factors of Vadha diseases. They are,

யூகி வைத்திய சிந்தாமணி - 800 :

'என்னவே வாதந்தா னெண்பதாகும்
இகத்திலே மனிதர்களுக் கெய்யுமாறு
பின்னவே பொன்தனையே சோரஞ்செய்து
பெரியோர்கள் பிராமணரைத் தூடணித்தும்
வன்தேவச் சொத்தில் சோரஞ்செய்து
மாதா பிதா குருவை மறந்த பேர்க்கும்
கன்னவே வேதத்தை நிந்தை செய்தால்
காயத்திற் கலந்திடுமே வாதந் தானே."
'தானென்ற கசப்போடு துவர்ப்புறைப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த வண்ணம்
ஆனென்ற வாறினது புசித்தாலும்
ஆகாயத் தேறலது குடித்தலாலும்
பானென்ற பகலுறக்கம் மிரா விழிப்பு
பட்டினியே மிகவுறுதல் பாரமெய்தல்

தேனென்ற மொழியார் மேற் சிந்தையாதல்
சீக்கிரமாய் வாதமது செனிக்குந் தானே."

'ஆனான வரன்றனையே மதியாமாந்தர்
அகதி பரதேசியர்கட்கு அன்ன மீயார்
கோனான குருமொழியை மறந்த பேர்கள்
கொலைகளவு பொய்காமங் குறித்த பேர்க்கு
ஊனான சடந்தன்னில் வாதம் வந்து
உற்பவிக்கும் வேதத்தின் உண்மைதானே."
'வாதவர்த்தி தனைகால மேதோ வென்னில்
மருவுகின்ற வானிகர்க் கடகமாகும்
ஆதவைப் பசியோடு கார்த்திகை தன்னில்
அடருமே மற்றமா தங்கள் தன்னில்
போதவே சமிக்குகின்ற காலமாகும்."

பரராசசேகரம்:

'பாரினிற் பயப்பட்டாலும் பலருடன் கோபித்தாலும்
காரெனக் கருகியோடிக் கழுமரத்துரத்தினாலும்
ஏர்பெறு தனது நெஞ்சின் மிகத்துக்கமடைந்திட்டாலும்
பாரிய காற்றினாலும் படரீனும் வாதங்காணும்"

அகத்தியர் குணவாகடம்:

'விவரமடா அசதி சன்னி மூளை நோவு
விரிவான மூளையது மிருதுவாகி
அவனிதனில் திடமாகப் போவதாலும்
அப்பனே மூத்திர குண்டிக்காய் வியாதியாலும்
தவமுனிவர் தீர்க்காக்கை மேக ரோகம்
தன்மையுள்ள முத்தண்டு கொடிவியாதி
அவமிலாப் பரிச நரம்பழுத்தங் கண்டால்
அணுகுமடா வாதநோய் ஆகும்பாரே."

அகத்தியர் கன்ம காண்டம்:

'நூலென்ற வாதம் வந்த வகைதானேது
நுண்மையாய்க் கன்மத்தின் வகையைக் கேளு
காலிலே தோன்றியது கடுப்பதேது

கைகாலில் முடக்கியது வீக்கமேது

கோலிலே படுகின்ற விருட்சமான

குழந்தை மரந்தன்னை வெட்டல் மேல்தோல்சீவல்

நாலிலே சீவசெந்து கால்முறித்தல்

நல்லகொம்பு தழைமுறித்தல் நலித்தல் காணே."

To sum up:

Diet:

- Excessive bitter, astringent, pungent taste foods.
- Harmful combinations like milk and greens.
- Eating tubers.
- Drinking polluted water.
- Previously cooked items.

Lifestyle:

- Day time naps.
- Overnight toil.
- Excessive physical strain.
- Walking long distances.
- Exposure to excessive cold.
- Mental fluctuations.

Seasonal changes:

- Precipitation of Vadha diseases generally occur during the winter season (Aani to Karthigai).

Siddha literature states that since the soul is immortal, the imprints of sins would be carried over from life to life and expressed via diseases. This theory of kanmam should be extensively studied and further analyzed.

நோய் வரும் வழி:

உணவாதி செயல்களாலும் கால - தேக நிலை மாறுபாடுகளாலும் கன்ம வினையாலும் வாதம் அதிகரித்து பித்த - கபங்களை கெடுத்து பின் ஏழு உடற்தாதுக்களை பற்றி நோய் ஏற்படுகிறது.

THE TYPE OF ALTERATIONS OF VATHA ARE

1. THANNILAI VALARCHI (தன்னிலை வளர்ச்சி)

DEFINITION

A Kutram, which is provoked in its own location, is called Thannilai Valarchi.

LIMITATION

Hatefulness of the things, which are causing thannilai valarchi, and likeness of things, which, are getting opposite properties are the limitations of Thannilai Valarchi.

DURATION

Vatha gets "Thannilai Valarchi" during Mudhuvenil Kaalam (Aani andAadi].

2. Vetrunilai Valarchi (வேற்றுநிலை வளர்ச்சி)

DEFINITION

A kutram, which is provoked to other locations, is called "Vetrunilai Valarchi".

LIMITATION

Signs and symptoms of the affected kutram and the pathological conditions of the Udal kattugal give details of the limitations.

DURATION :

Vatha Gets "Vetrunillai Valarchi" during Kaar Kaalam [Aavani and Purattasil.

3. THANNILAI ADAITHAL (தன்னிலை அடைதல்)

DEFINITION

A provoked Kuktram, which is neutralizing in its own property, is called Thannilai Adaithal.

DURATION

The provoked vatha neutralizes during Koodhir Kaalam (lyppasi and Kaarthigaij.

ஆனி, ஆடி, ஆவணி, புரட்டாசி, ஐப்பசி, கார்த்திகை இம்மாதங்களில் வாதம் மிகுந்து வேதனை தரும். மற்ற மாதங்களில் வாதம் சமனடையும்.

FACTORS WHICH ALTER VATHA

1. When hot foods are mixed with vayu, vatha gets "Thannilai Valarchi".
2. When cold is mixed with vayu, vatha gets "Vetrunilai Valarchi".
3. And when oilyness mingles with hotness and gets are mixed with vayu, vatha neutralizes in its own property that means healthy conditions.

CHARACTERISTICS OF VATHA THEGI :

ACCODING TO SIDDHA MARUTHUVAANGA SURUKKAM :

- வாத உடலினனுக்குத் தீயும் ஐயமும் குறைந்து வளி மிகுந்திருப்பதுமன்றி, மெலிந்து உயர்ந்த உடலும்,
- பருத்த அடித் தொடைகளும், நடந்தால் கீல்கள் நெட்டையிடுதலும்,
- தடித்த இமைகளுடன் வட்டமாக விகாரித்துச் சாக்கண் போன்று சுரசுரப்பாயும்,
- குளிர்ந்தபார்வையும், சிறுது கறுமை வெண்மை கலந்தனவாயுமிருக்கும் கண்களும்,
- சிறுதுவெண்மை கலந்து ஒளிரும் உடல் நிறமும் அவ்வாறு கறுத்து முனை பிளந்த தலைமயிரும்,
- தெளிவான வார்த்தையையும் சில வேளை மனக்கலக்கத்துடன் பட்டும் படாமையுமான தடுமாற்ற வார்த்தையும்,
- தித்திப்பு புளிப்பு, உப்பு, சூடு உள்ள பொருள்களில் சிறுது விருப்பமும்,குளிர்ச்சி பொருந்திய பொருள்களில் வெறுப்பும்,மிக்க உண்டியும், மிக்க உண்டியெனினும் அற்ப வன்மையும்,
- பெண்களிடத்தில் அற்பவிருப்பும்,
- வீரிய வளர்ச்சிக் குறைவும்,
- புத்திர பெருக்கமும், ஆண்மை உணர்ச்சி அறிவு இவை நிலையின்னையும்,
- விளையாட்டு, இசை அவமதிச்சிரிப்பு, தொக்கணம், வேட்டையாடலில் விருப்பும்,
- தகுதி இன்மை, பகைமை,ஈகையின்மை, பொன்னாலான பொருள்களை கவர்தலில் நினைப்பு முதலிய பண்புகளும் புகழின்மையும்,
- அரைக்கண் மூடிய சிறு தூக்கமும், அத்தூக்கத்தில் வீண், மலை, காடு இவைகளில்தான் நடப்பதாகக் காணுகின்ற கனவும், புலமைத் திறமையையும் உண்டாயிருக்கும்.

-சித்த மருதது வாங்கச் சுருக்கம்

According to Sidha Maruthuvaanga Surukkam,

Vatha thegi has an appearance of

- Thin, tall built
- Large thighs
- Thickened eyelids
- Round, small, white, mixed eyes
- Cool sight Black and white coloured skin complexion
- Black, diverten hairs
- Clear Speech – some times slurring, digressing speech etc

Pathophysiology:

Diet, Seasonal changes, Lifestyle variations and Psychosocial factors causes imbalance in the basic elements altering the ratio of three humours and leads to the derangement of seven udal thaathus producing the disease symptoms.

The five basic elements:

Earth:

- It represents the Solidity.
- It gives shape to the body and releases its energy.
- Bones, muscles, nerves, skin, hair represent the Earth in the body.
- Stability, strength, growth, firmness, sturdiness are its characters.

Water:

- It represents Fluidity.
- Makes the Earth supple and helps in the transmission of energy.
- Serum, lymph, saliva, sweat, semen represent it in the body.
- Smoothness, gracefulness, volatility, agility, flexibility are its characters.

Fire:

- It represents warmth.
- It gives vigor and stimulation to the body.
- Hunger, fear, anger, irritation represent it in the body.

- It controls digestion.
- Heat, dryness, sharpness, illumination, are its characters.

Air:

- It represents gas atmosphere.
- It works as a life carrier.
- Respiration and nervous system are controlled by it.
- Walking, running, standing, sitting, jumping like postures represent it in the body.
- Aridity, parchedness, wryness, sadness are its characters.

Ether:

- It is the eternal space and creator of life.
- The eight indispensible passions represent it in the body.
- Infinitesimal nature, clarity, subtleness, delicacy, refinement are its characters.

The derangement of FIVE ELEMENTS in Thandaga Vatham is as follows.

S.No.	**Element**	**Nature of derangement**	**Effect**
1.	Earth	↑	Osteophytes
2.	Water	↓	Giddiness (Decrease blood supply).
3.	Fire	↑	Breaking the Cartilage Fragments.
4.	Air	↑↑	Swelling and Pain, Mental Depression.
5.	Ether	↓↓	Joint Space Narrows.

Three humours:

Vadham:

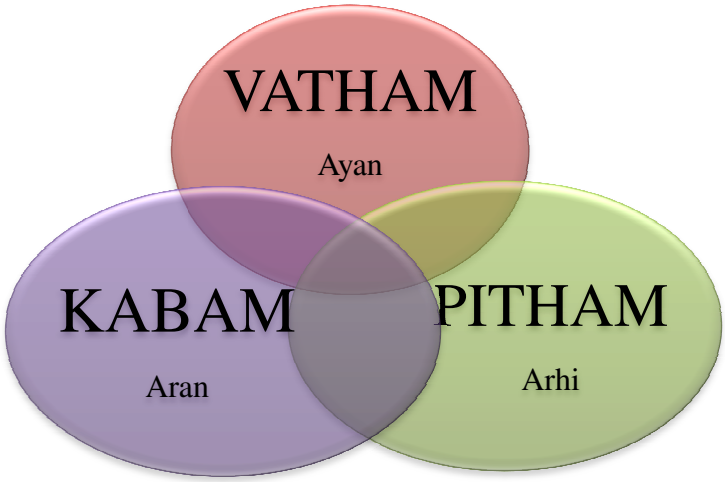
- Formed by air and ether.
- Construction, dryness, cool, minuscule, hardness, movement, buoyancy are its properties
- Skin, bone, muscles, nerves, joints are the seats of vadham.
- It controls the senses, respiration, emotion, speech, etc.
- It causes pain, numbness, spasticity, flaccidity, tremors, muscle wasting, inflammation, thirst, constipation, dryness, loss of movements, loss of integrity, hyper pigmentation etc if affected.

Pitham:

- Formed by fire.
- Protection, warmth, sour, liquidity, transparency are its properties.
- Blood, lymph, eyes, stomach are it seats.
- It performs the functions of digestion and controls taste, hunger, thirst etc.
- It also controls intellect.
- If deranged it causes giddiness, anorexia, fever, jaundice, anaemia etc.

Kabam:

- Formed by earth and water.
- Destruction, softness, sweetness, frothiness, flimsiness are its properties.
- Intestine, liver, brain, thorax are its seats.
- It gives lubrication to the joints, strength to joints.
- Its derangement leads to loss of strength and steadiness, vertigo, palpitation etc.



VATHAM:

- Improves the sensory organ
- Improves the speech
- Stabilizes the mind
- Controls respiration and gives more energy.

CITATION:

- Abanan
- Faeces
- Idakalai
- Below the umbilicus
- Lumbar spine
- Skin
- Nerves
- Joints and hair follicles
- Muscles

It represents vayu, mind, dryness, pain, flatulence, sensitiveness and lightness.

Pranan:

- Regulates respiration
- Controls mental function and special senses.

Abanan:

- Excretes urine and faeces
- Expulsion of semen and fetus

Viyanan:

- Promotes circulation and strengthens the nervous system
- Responsible for the recognition of various sensation

Uthanan:

- Responsible for the functions of the speech
- Reflexes like vomiting, hiccough, cough etc.,

Samanan:

- Assimilation process

Nagan:

- Responsible for intelligence
- Movement of eyeball

Koorman:

- Responsible for the sensory functions of eyes
- Promotes lacrimination

Kirukaran:

- Increases salivation in the oral cavity and mucous secretion in the nasal cavities
- .Increases appetite and helps in concentration

Thevathathan:

- Responsible for laziness.
- Eyeball movements.

Thananjeyan:

- Escapes after death from body

In thandaga vatham Abanan, Viyanan, Samanan , Thevathathan may be affected.

PITHAM:

Analagam: Responsible for digestion

Ranjagam: Gives nutrition to blood

Sathagam: Responsible for willful activities.

Prasagam: Gives luster to skin.

Alosagam: Gives strength to eyes

Sathagam is affected in thandaga vatham

KABAM:

Avalambagam: Controls other kabams

Klethagam: It lubricates the food.

Bothagam: Responsible for taste sensation

Tharpagam: It acts as a coolant for eyes.

Santhigam: It maintains the integrity of joints.

Avalambagam and Santhigam are affected in thandaga vatham.

UdalThathukal:

There are seven udal thathukkal in human body.

Saram	Strengthens the body and mind	Affected
Senneer	Preserves brightness, boldness, power and knowledge.	Not Affected
Oon	Gives structure and shape to body. Represents the tissues.	Early stage – not affected. Later stage – Affected

Kozhuppu	Lubricate the joints.	Affected
Enbu	Physical bone structure.	Affected
Moolai	It is present in the bones and gives strength to them	Affected

THANDAGAVATHAM:

Thandagavatham is one among the 80 vatha diseases with the clinical symptoms of:

- ❖ Pain starts at the lower back gradually it moves upwards due to causative factor the Vayu travels in such a way.
- ❖ Excessive sweating
- ❖ Reduced range of movements
- ❖ Anaemia
- ❖ Yellow discoloration of urine and faeces
- ❖ Aggrevating factor affects the bones and nerves,not able to walk.

ACCORDING TO YUGI VAITHIYA CHINTHAMANI :

‘வழுத்தவே மூலாதாரத்தைப் பற்றியே
மருவியே மேலேறி முதுகு மட்டாய்
விழுத்தவே சிரசில் வந்து வியர்வுமாகி
விகுவாக நோவாகி மேனி கன்றி
பழுதத் வே உடம்பெங்கும் பஞ்சு போலாம்
பாங்கான மலசல மஞ்ச்ளாகும்
குழுத்தவே தெண்டகமாம் வாதந்தன்னைக்
கூறினோங் குணமெல்லாங் கூர்ந்து பாரே”

-யூகி வைத்திய சிந்தாமணி பாடல் 288

‘கூர்ந்திட்ட மலசலங்கள் துரிதமானால்
கொண்டடக்கிப் பின்புதான் கொடிதாய் தள்ளி
ஊர்ந்திட்ட சரீரத்தி லுதிர மீறி
ஊறத் தேய்த்து தலையதனி லெண்ணெய் வார்க்கில்
வூர்த்திட்ட வழி நடக்கில் மெத்த வுந்தான்
வுாதந் தானுறப் வித்து நடை கொடாமல்

நார்ந்திட்ட நரம்போடு எலும்பிற் சூழந்து
நணுகியே யோடி நெஞ்சி வேறுந் தானே

-யூகி வைத்திய சிந்தாமணி பாடல் 289

யோகத்தின் முதல் நிலையில் நுழையும் போது உண்டாகும் கேட்டால், முதுகுத் தண்டின் கீழ்ப்புற மிருந்து தலை வரையிலும் கிளம்பிய வாயுவினால் ஏற்படும் நோயாகும். இந்நோயில் வியர்த்தல், உடல் இறுகுதல், வலித்தல், உடல் பழுத்துப் பஞ்சு போல் வெளுத்தல், மலமும் சிறுநீரும் மஞ்சளாதல் என்னும் குறி குணங்களை காட்டும்.

தண்டக வாயுவிலுண்டாகும் கழிச்சலை அடக்கி வருவதலால் சின்னாட்கள் சென்ற பின்பு அக்கழிச்சல் அடக்க முடியாத அளவில் மிகுந்து கழியத் தொடங்கும்.

அதனால் உடல் முழுமையுள்ள குருதி தன்னளவில் மிகுந்து பாயும். அன்றியும் இந்நோய் முழுமையும் போகாதிருக்கையில் தலை முழுகல், அதிக தொலைவுநடத்தல் இவற்றை மேற்கொள்ளில் வளிக்குற்றம் மிகுந்து நரம்பு, எலும்புகளை பற்றிச் சூழ்ந்து நடக்க முடியாமற் செய்து அவ்வாயு நெஞ்சு வரையும் பாயும்.

CAUSATIVEFACTOR:

- Due to wrong yogic practices at the joint level,vayu gets started from lower back andreaches the head and causes the disease.

AGGREVATING FACTOR:

- Head bath
- Walking for a long distance

ACCORDING TO ROGA NIRNAYASARAM :

‘தேகம் தண்டத்தைப் போல் விழுந்து அசைவில்லாமல் இருக்கும்”

-ரோக நிர்ணய சாரம்

- Body is rendered like a log of wood.

ACCORDING TO THANVANTHIRI VAITHIYAM :

“ஆமகட்ட தனால் வாயு வதிகமாய்ச் சிலேற் பனத்தைத˙
தூமகட்டாகச் சேர்த்துத் தடித்திடுஞ்ச் சாரீ மெல்லாம்
நோமக் கட்டான மேனி நுவலிளைப் பெயர்ப்புத் தோன்றும்
தூமக் கட்டான ரோகந் தண்டக வாதமாமே”

-தன்வந்தரி வைத்தியம்

ஆமத்துடன் வாயு அதிகரித்து கபத்துடன் சேர்ந்து சரீரத்தை ஸ்தூலிக்கச் செய்யும். சரீரம் வாட்டமடையும்.

- Generalized odema
- General weakness

ACCORDING TO JEEVARATCHAMIRTHAM :-

வாயுவானது எண்ணெய் வஸ்து, மந்தவஸ்து, சீர வீரிய வஸ்து, தயிர் அதிகலவணம், பகல் நித்திரை, பதினான்கு வேகங்களை மறித்தல் ஆகியவற்றால் பிறந்துசப்ததாதுக்களிலும் வியாபித்து அவைகளைக் கலைத்துவிட்டு ஆமாசயஸ்தானத்தைஅனுசரித்துச் சிலேத்ம பித்தங்களைத் தன்னுடன் சேர்த்துக் கொண்டுஅவயவங்களின் செயலை மாற்றிவிடும். இதனால் ரசாதி தாதுக்களில் மரத்தல்,சீதளம், உள்ளெரிச்சல், சரீரங் கனத்தல், ஞாபகமறதி, பிரமை, சுழலல் போலிருத்தல்,இளைப்பு, அதிக வேதனை, நீர்க்கட்டு என்னும் இக்குறிகுணங்களோடு தேகமானதுதண்டத்தைப் போல விழுந்து அசைதலும் நீட்டல் முக்கலும் எழுதலும்இல்லாதிருக்கும். இது தேகத்தை தண்டைப் போல நீட்டி விடுதலால் தண்டக வாதம்எனப் பேர் பெற்றது.

-அனு போக வைத்திய தேவரகசியம் (முதல் பாகம்)

- Numbness
- Burning sensation
- Loss of memory
- Giddiness
- Dyspnoea
- Body pain
- Unurea
- Body is rendered like a log of wood
- Restricted movements

PINIYARIMURAIMAI - DIAGNOSIS

Pini yari muraimai means method of finding the diseases.

Piniyari Muraimai - Pini + Yari + Muraimai

Pini Means - The disease which catch the body

Yari means - Identifying the diseases

Muraimai means- Rules and methods

As per siddha literature, the diagnosis is based upon three main principles.

1. Poriyalarithal
2. Pulanal arithal
3. Vinaathal

Poriyalarithal and pulanalarithal:

Poriyal means five organs of perception pulangal means five objects

Porigal Pulangal

1. Nose - Smell
2. Tongue - Taste
3. Eyes - Vision
4. Skin - touch
5. Ear - Sound

The application of poriyalarithal and pulanalarithal form the fundamental stepin the diagnosis of a disease.

Vinaathal:

It is asking questions concerned with the history of disease, and its clinical symptoms etc., to the patient (or) asking to his neighbour, when the patient is not able to speak, or the patient to be a child' These three principles are affected through the Envagai thervugal.

The diagnosis is made through a proper examination of human body known as Envagai thervu. They are,

‘நாடிப் பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவ ராயுதம்”
- நோய் நாடல் பாகம்I

- Na - Examination of the tongue
- Niram - Examination of skin colour
- Mozhi - Examination of oral cavity and speech
- Vizhi - Examination of eye
- Malam - Examination of faecal matter.

  In thandagavatham there is constipation.
- Moothiram - Urine analysis

‘அருந்துமாறி ரதமும் அவிரோதமாய்
அ.்.கல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியே காதுபெய்
தொரு முகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே”

- நோய் நாடல் பாகம் I

1. Neerkuri- The four aspects of this are,
    - Colour
    - Odor
    - Specific gravity
    - Deposits

‘வந்த நீர்க்கரிஎடை மணம்நுரை எஞ்சலென்
றைந்தியலுளவவை யறைகுது முறையே”

2. Neikuri –

This is special technique for diagnosing specific for Siddha system of medicine. A drop of oil is dropped inurine; the shape in which it spreads is noted and compared with standard list provided by the Siddha literature.

- Sparisam - Analysis of texture, temperature through touch

Finally the most important

- Naadi or pulse examination.

The three Uyir thaadhus are formed by the combination of

Idagalai + Abanan - Vadham

Pingalai + Pranan - Pitham

Suzhumunai + Samanan - Kabam

Derangement in the ratio leads to various diseases. The naadi can be felt one inch below the wrist on the radial side by means of palpation and percussion with the tip of the index, middle and ring finger corresponding of Vatham, Pitham and Kabam respectively. The normal ratios of three humours of the body are 1:1/2:1/4 respectively.

‘கரிமுகனடியை வாழ்த்தி கைதனில் நாடி பார்க்கில்
பெருவிரலங் குலத்தில் பிடித்தடி நடுவே தொட்டால்
ஒரு விரலோடில் வாதம் உயர் நடுவிரலில் பித்தம்
திருவிரல் மூன்றிலோடில் சிலேத்துமம நாடிதானே”

-நோய் நாடல் பாகம்I

InThandaga vatham the Naadi is either Vadha Pitham or Pitha Vadham.

Geographical, Seasonal and Personal variations (nilam, kalam, theganilai) are taken into consideration for the diagnosis of the diseases.

GEOGRAPHICAL VARIATION:

The geographical distribution of the land is classified into five types.

- Kurunji – Kabha diseases and liver diseases are common.
- Mullai – Pitha and Vadha diseases are common.
- Marutham – Safest place to reside.
- Neithal – Vadha diseases are common.
- Paalai – All the three humours may be affected.

SEASONAL VARIATIONS:

- Kaar kalam – August 16 – October 15.
- Koodhir kalam – October 16 – December 15.
- Munpani kalam – December 16 – February 15.
- Pin pani kalam – February 16 – April 15.
- Ilavenil kalam – April 16 – June 15.
- Mudhuvenil kalam – June 16 – August 15.

PERSONAL VARIATIONS:

- Vatha thegam
- Pitha thegam
- Kabha thegam

DIFFERENTIAL DIAGNOSIS:

Other vatha disease, which resembles thangaga vatham are mentioned below.Caution of patient history taking and examination will help to diagnosis the diseasewithout any doubt.

They are

1. Aasuva thamba vatham
2. Ooruthamba vatham

1. ஆசுவதம்ப வாதம் :

‘வாதமா யுடல்கெ வளுத்து வழவெல்லா நேரம்
முயக்கமோ டிருமலா யூனை யுண்டாம்
நேதமாய் நெஞ்சடைத்தப் பொறி கலங்கும்
நெருபப்பாக உடல் காணு நெடுமூச்சுண்டாம்
கோதுதான் மயக்கத்தில் மருந்திட்டால்
குளிர்ச்சியாய்க் கோபிக்குங் கூச்ச லுணட்டாம்
பாதநத்தான் திமிருணட்டாய் முடபோலாகும்
படுத்த ஆசுவதம்பம் பகரலாமே
பகரவே வாதமது கோபித்தப்போ
பண்பாக ஸ்திாகர்டி யதுதான் செய்யில்
நகரவே வெகுதூர வழி நடக்கிலவ்
நளிரான காற்றுமே பனிமேல் பட்டால்
மிகரவே காய்கள் கனி கிழங்கு தன்னை
மிகவருத்தி மீறியேய் தயிர்தான் கொண்டால்
முகரவே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலுங் கணைக்காலுங் கடுப்புண்டாடே”

-யூ.கி.வை. சிந்தாமணி

The Clinical features are :

1. Paleness of the body
2. Cough
3. Chest heaviness
4. Numbness of both lower limbs.

2. ஊருத்தம்ப வாதம் :

‘ஆமென்ற வாதமது உள்ள டங்கி
ஆடித்துடைதான் குறங்கிரண்டு மலவாய்ப் பற்றி

காமெனற் கைகாலில் விரலு சுற்றிக்
கனத்துமே சாணியது பொதிந்தார் போலத்
தேமென்ற சிரந்தனிலே பார முண்டாய்த்
தேமெங்கு மூதியே திமிருண் டாகும்
நாமென்ற நடக்கொணர வொடுக்க மாகி
நலியூருந் தம்பமது நனுகுங்கானே"

The clinical features are

1. Heaviness in both thighs
2. Feelings of cow waste applied over fingers of both hands and feet
3. Numbness feel in whole body
4. Difficulty in walking.

LINE OF TREATMENT

According to Siddha system of medicine, any disease management has three stages.

- Kaapu or Prevention.
- Neekam or Treatment.
- Niraivu or Restoration.

KAAPU OR PREVENTION:

- Avoid excessive weight lifting.
- Maintain proper posture while sitting.
- Sleep without pillows.
- Avoid watching television for a long period.
- Avoid excessive cold exposure.

NEEKAM OR TREATMENT:

The main aim of treatment in Siddha system is equlizing the lost equilibrium in three humours. Hence the below order is followed in the treatment of thandaga vadham.

- Purgatives
- Internal and external medicines.
- Diet and advises.
- Kanma neekam.

1. **PURGATIVES**:

The purgatives are given to correct the deranged Vadham.

‘விரேசனத்தால் வாதம் தாழும்”

Mostly used purgatives are,

- Vellai ennai – 10 – 15 ml

2.**INTERNAL AND EXTERNAL MEDICINES:**

Internl and external medicines are given to cure the diseases.

3. **DIET AND ADVISES**:

Pathiyam or dietary regulations should be strictly followed while taking internal medicines. If not followed it may antagonize drug effect and can produce unwanted results.

‘பத்தியத்தாலே பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன் போகும்- பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதருக் காதலினாற்
பத்தியமே வத்தியென்று பார்”

-தேரையர் வெண்பா.

4. **KANMA NEEKAM**:

To expiate the effects of kanmam, following measures are advised.

‘வையடா செவ்வந்தி முளரிதானும்
வாகான கிணறுகளும் சாலை சோலை”

-அகத்தியர் கன்ம காண்டம்

NIRAIVU OR RESTORATION:

Any residual effects of the disease should be cleared and the patient should return to his normal life. To restore the activities of the life, special threapy is much essential.

SIRAPPU MARUTHUVAM

All of the three stages of management of Thandaga vadham can be done by the application of SIRAPPU MARUTHUVAM (Special medicine), which is the unique feature in Siddha system of medicine.

- ❖ KARPAM
- ❖ YOGAM
- ❖ VARMAM
- ❖ THOKKANAM

These are the specialty in SIRAPPU MARUTHUVAM.

1.KARPAM:

Karpam or rejuvenator acts at molecular level and delays cellular ageing, thereby fights the progressive degeneration, is magnificent concept of Siddhars. It may be herbal, mineral or animal product. Some of the Karpam useful in Vadha diseases are

- Inji (Gingiber officinalis)
- Erukku (Calotrophis gigantea)
- Seenthil (Tinospora cordifolia)
- Amukura (Withania somnifera)
- Kodiveli (Plumbago zeylanicum)
- Parangi pattai (Smilax chinensis)
- Serankottai (Semecarpus anacardium)

2.YOGAM:

Yogam is defined as the union of the individual spirit with the universal spirit or attaining oneness with God. Astanga yogam defines eight steps of accomplishing enlightment.

‘இயம நியமமே எண்ணிலா ஆதனம்
நயமுறு பிராணாயாமம் பிரத்தி யாகாரம்
சயமிகு தாரணை தியானம் சமாதி
அயமுறும் அட்டாங்கம் ஆவது மாமே”

-திருமந்திரம்.

- Purity in thought.
- Purity in action.
- Proper postures.
- Breathing exercises.
- Restraining five senses.
- Concentration.
- Meditation.
- Submission and attaining oneness with God.

A. **Asanam**: (Proper postures)

Asana means a state of being in which one can remain physically and mentally steady, calm, quiet and comfortable. Asana are specific body positions which opens the energy channels. They are tools to higher awareness and provide the stable foundation for our exploration of the body, mind and the soul.

Some of the asana useful in thandaga vatham are,

- Chakrasanam – wheel pose
- Thanurasanam – bow pose
- Salabasanam – locust pose
- Paatha hasthasanam
- Ushtasanam

MECHANISM OF PAIN RELIEF:

1. **Action on spinal muscles** :

Asanam dampen the inflow of sensory impulses to the brain, which causes the less stimulation to the emotional brain. Therefore, there are less visceral disturbances. Further reduction of sensory input creates a reciprocal chain, relaxing the muscle. Inhibition of synapses due to relaxed neuro muscular junctions in turn reduces the sensory input further.

2. **Effects on tendons and ligaments**:

The accentuated curve of the spine makes it supple and mobile. The action on the ligaments and tendons of the spine has important effects on the nervous activity.

3. Effects on nervous system:

Asanam generate reflex actions in the vegetative functions and tones the chains of ganglions situated on both sides of the spine.

B. Pranayamam:

PRANAN means bioenergy. IYAMAM means control. Hence pranayama means control of bioenergy.

‘ஏற்றி இறக்கி இருகாலும் பூரிக்கும்
காற்றை பிடிக்கும் கணக்கறி வாரில்லை
காற்றை பிடிக்கும் கணக்கறி வாளர்க்கு
கூற்றை உதைக்கும் குறியது வாமே”

-திருமூலர்.

USES OF PRANAYAMAM:

- It improves the vital capacity.
- Improves circulation.
- Aids concentration.

3.VARMAM:

The points where the energy source resides and flows in the body of a living organism are known as varmam. If it is hurt in a particular manner, that forces some symptoms and signs in the human body, according to the site of injury.

We can use these points in constructive way to cure diseases, relieve pain, preserve body etc. It can also be used defensive or attack stance, with techniques as in varma kalai, kalaripaayathu etc.

The varmam points useful in thandaga vatham are

- ✓ Manibandha adangal
- ✓ Komberi kaalam
- ✓ Kuthikaal varmam
- ✓ Kaaal kulasu
- ✓ Kanpugaichal
- ✓ Viruthi kaalam
- ✓ Sevikutri kaalam
- ✓ Mudichu varama
- ✓ Nai iruppu varmam
- ✓ Puratharai
- ✓ Ulthodai varmam
- ✓ Boomi kaalam

4.THOKKANAM:

Thokkanam or massage is a relaxation technique very much useful in vadha diseases.

‘தொக்கணத்தி னாலிரத்தந் தோல் ஊனிவைகட்கு
மிக்க சவுக்கியஞ் சமீரனும் போம் - மெய்க்கதிக
புட்டியுறக்கம் புணர்ச்சியிவை கதிக்கும்
பட்ட அலைச்சலறும் பார்”-தேரன் தரு.

Benefits:

- ➢ Improves blood and lymph circulation.
- ➢ Reduces nerve irritation.
- ➢ Refreshes the tissues.
- ➢ It may also reduce the level of stress hormones.
- ➢ Produces endorphins and gives happiness.

MODERNASPECTS

AnatomyofVertebralColumn:

The vertebral column forms back bone of the body. It forms a part of the axial skeleton. It is made up of 33 pieces of vertebrae and in intervening intervertebral discs. It is 60-70 cm length.

AnatomyoftheSpine

The spine is a complex structure that provides structural support for the body, transmits the weight, allows movement,protect the spinal cord and exiting nerve roots and act as an attachment site for the muscles and ligaments.

CurvaturesofSpine:

Normal curves present in sagittal plane with lordosis on the cervical and lumbar spine and Kyphosis in the thoracic spine. These normal curves allow for improved flexibility and load bearing capacity of the spine.

The cervical and lumbar spine vertebrae are highly mobile as compared to the more rigid thoracic vertebrae that are restrained by the ribcage.

IntervertebralDisc:

It is a fibro cartilaginous space found between the vertebral bodies. It is composed of inner nucleus pulposus and outer annular fibroses.

LUMBARVERTEBRAE

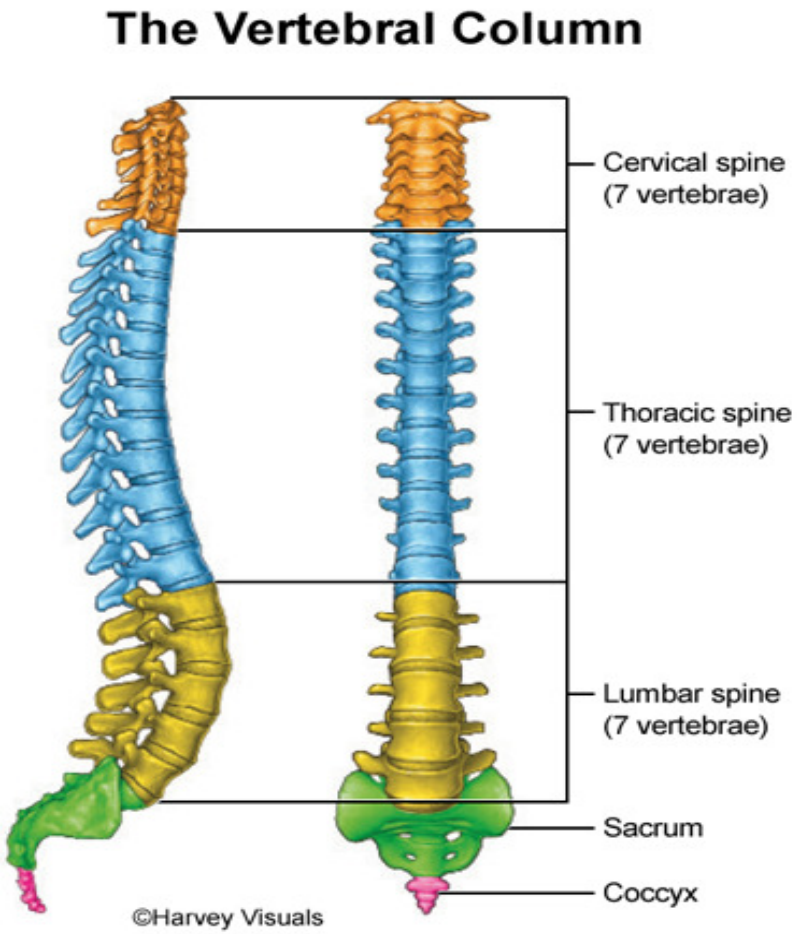
It consist of 5 individual cylindrical boes that forms the spine in the lower back in which the first four are typical and the fifth is atypical.

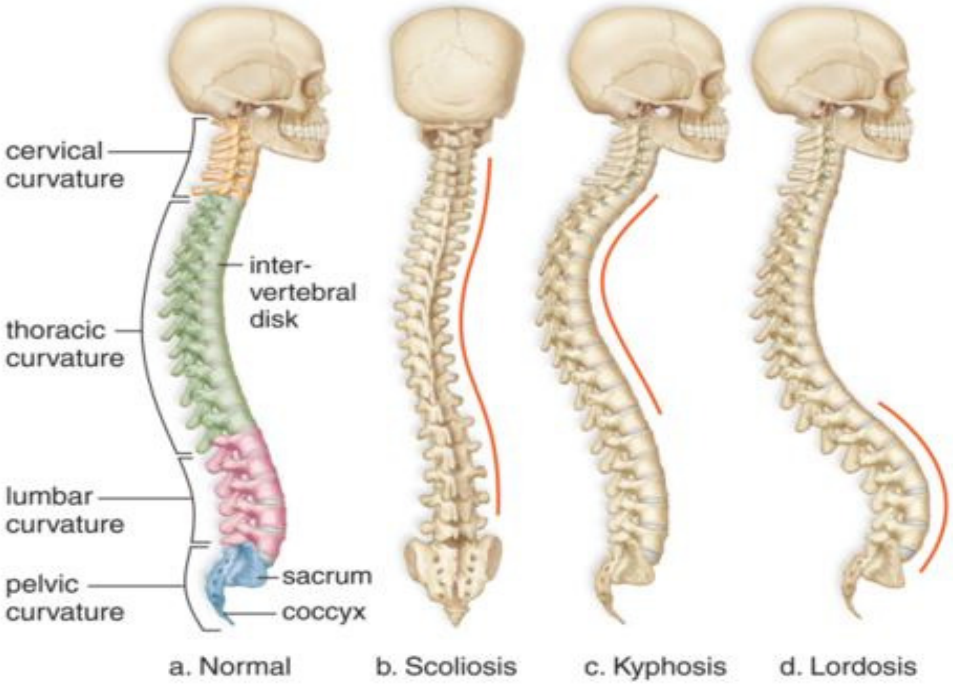
Typicallumbarvertebra:

- Body is large and is wider from side to side than from before to backwards.
- Vertebra foramen is triangular in shape and is larger than thoracic region.
- Pedicles are short and strong. They project backwards from the upper part ofbody.
- Laminae are short and thick board. They are directed and medially.
- The spine form a vertical quadrilateral plate direct backwards and downwards.
- The transverse processes are thin and taping, are directed laterally and slightlybackwards.
- The superior articular processes lie farther apart than inferior. Each process bears a concave facet facing medially. Inferior articular process lies nearer to each other than superior.

FIFTHLUMBARVERTEBRAE

- ❖ Body is largest of all lumbar vertebras.Anterior surface is deep.
- ❖ Pedicles are directed backwards and laterally.
- ❖ The spine is small and short.
- ❖ The transverse processes are small short and pyramidal in shape.
- ❖ The superior articular facets look more backward than medially and inferior articular facet look more forwards.
- ❖ The distance between the inferior articular processes is equal or more than thedistance between the superior articular process.





ANATOMY OF LUMBAR VERTEBRAE:

- These vertebrae carry all the upper body weight which provides the flexibility and movements to the trunk region.
- The lumbar vertebrae make uo the region of the spine inferior to the thorax and superior to the sacrum and coccyx in the pelvis.
- It connects the each vertebrae to its adjoining vertebra,it is called intervertebral disc,made up of tough fibrocartilaginous jelly like centre.
- The outer layer of the intervertebral disc is annulus fibrosis which holds the vertebra together and provides the strength and flexibility to the back during movement.
- The jelly like nucleus pulposus acts as a shock absorber to resist the strain and the pressure exerted on the lower back.
- A cylinder of bone known as the vertebral body makes up the majority of the lumbar vertebral mass and bears most of the body weight.
- Posteriorly the body is connected to a ring of bone known as the arch.The arch surrounds the hollow vertebral foramen and connects the body to the bony process on the posterior of the vertebra.
- The vertebral foramen is a large,triangular opening in the centre of the vertebra thar provides the space for spinal cord,cauda eqina and meninges as they pass through the lower back.

The muscles around the lumbar spine can be divided into 3 group of muscles because of position and function:

1. **Psoas major** attaches directly to the vertebral bodies anterolaterally and acts as a primary flexor muscles of the hip joint.
2. **Quadratus lumborum** and the **lateral intertransversarii** attach to and covers the transverse process anteriorly.They act merely at lateral flexors.
3. **Interspinalis,anterior transversarii medialis, multifidi, lumbar erctor spinae (longissmus and iliocostalis).**They attach directly to the lumbar vertebraeand acts as a extensor muscles.

LUMBAR SPONDYLOSIS:

SYNONYMS:

- ✓ Lumbar arthrosis
- ✓ Lumbar spomdylitis
- ✓ Hypertropic arthritis
- ✓ Osteoarthritis of lumbar spine

DEFINITION:

Lumbar spondylosis defined as any or all degenerative conditions affecting the vertebral bodies, inter vertebral disc and associated joints of the lumbar spine.

Nomenclature:

Lumbar - Lower back region

Spondylo - Vertebra

Osis - Condition

ABOUT LUMBARSPONDYLOSIS:

- ❖ Arthritis of the spine is called spondylosis.It differs from arthritis in other joints because of the effect of the discs between the vertebra,not just the small facet joints that are in pairs between two vertevrae.
- ❖ It is important to understand that arthritis does not mean pain.It is really just a wearing process in which some people can experience pain and in others there is no pain.
- ❖ Spondylosis does not have to cause a pain.If you get pain, it is usually from the lower back region but it can sometimes affect the higher lumbar areas.
- ❖ Symptomsusually relate to one main structure that is primary pain source, such as a facet joint.

- ❖ Occasionally, more generalized arthritis can cause pressure on to the spinal cord.This is called spinal stenosis.Because the spondylosis may result in pressure on the nerve going to the leg.It may not cause pain just numbness or pins and needles.
- ❖ More advanced spondylosis will certainly causes stiffness in the spine and may alter the posture with scoliosis or commonly a flattening of the lumbar lordosis.

Causes of lumbar spondylosis:

- Aging , syptoms notice at age of 20-60
- Genetic
- Arthritis of other joints such as neck,knee shoulder
- Injury history
- Constant sitting for a long period of time, poor posture
- Lifting heavy objects
- Overweight and obesity

Signs and symptoms:

- ❖ Frequent lower back pain
- ❖ Tenderness
- ❖ Tingling and numbness
- ❖ Motor weakness
- ❖ Above symptoms radiate to the lower extremities
- ❖ Restriction in lower back movements
- ❖ After prolonged activities such as sitting,standing and walking
- ❖ After inactivity, eg., getting up from bed after sleep
- ❖ Stiffness in morning

LOW BACKACHE:

- It's occurs common in second to fifth decade, disc disease and disc herniation occur in 3rd and 4th decade.
- Symptoms of low back pain, radiating to the buttocks and reduced by rest andin squatting position.
- Pain Increased while bending forward and sitting, weight lifting, coughing etc.,

RADICULOPATHY:

- Sciatica – Pain in supply of sciatic nerve and is regularly due to disc herniation
- It is evidenced by the leg pain, equal to or more than the back pain
- Pain radiating to sacroiliac region, buttocks and thighs.

NERVE ROOT COMPRESSION:

- About 95% of disc prolapse takes place through L4 - L5 region compressingL5 nerve root.
- The other disc prolapse takes place through L3 – L4 and L5 - S1 L4 and S1.

Epidemiology:

Lumbar spondylosis is seen in 80% of population.

Gender:

Out of which Men - 84%

Women - 74%

Age:

At the age between 55-64 yrs 30% of men and 28% of women are affected.

At the age between 45-55 yrs, 20% of men and 22% of women are affected.

Pathogenesis of Lumbar Spondylosis :

Degenerative changes begin with intervertebral disc desiccation, which is associated with increase in the ratio of keratin sulfate to chondroitin sulfate. Along with desiccation, the nucleus pulposus shrinks, loses elasticity, and becomes more fibrous due the loss of water, protein and mucopolysaccharides during the aging process. Disc height is initially lost in the ventral portion of the disc, which results in a decrease in lumbar lordosis. Unfortunately, this process results in positive feedback cycle due to the increase in forces applied ventrally and eventually may lead to kyphotic deformity.

Another early degenerative change is the posterior longitudinal ligament beginning to pull away from the vertebral bodies near the end plates. Eventually,abnormal lumbar movement result either from the pain of disc herniation or annular protrusion, worsening degenerative changes, or increased ligamentous laxity. Where the PLL peels off the dorsal vertebral body, reactive bone formation begins forming spondylotic bone spurs, which may be as large as the width of the vertebral body.

These osteophytic growths may project into the intervertebral foramina. The increase in joint motion causes an acceleration of osteophyte growth. The growth of

osteophytes, along with degenerative changes, leads to decrease in sagittal spinal canal diameter, the main pathophysiological process in Lumbar spinal spondylosis.

In addition to the above-described osteophytic and degenerative changes, athird modality that causes spinal canal narrowing is congenital Lumbar stenosis. The average Lumbar spondolytic patient's spinal canal is 3 mm smaller than the average population. More pronounced narrowing is observed in congenital stenosis patients.

The average adult spinal canal diameter has been reported to be 17 to 18 mm

Late Pathological Features :

As discussed earlier, osteophytes originate from the vertebral bodies andextend into the spinal canal while some eventually progress to cross the intervertebraldisc space. When this occurs, the vertebral bodies may combine and fuse.

If thisautofusion occurs, patients may experience a paradoxical increase in stability of their Lumbar spine. This autofusion also results in decreased Lumbar motion and may be responsible for the improvement of symptoms in patients with mild or moderate myelopathy. However, this process occurs in the setting of relative kyphosis and may place additional stress on adjacent Lumbar levels and lead to progression of spondylotic abnormalities at the rostral and caudal levels.

Degenerative changes begins with intervertebral disc desiccation Via Increase in the ratio of Keratin Sulfate , Nucleus pulposus shrinks, loses elasticity and become more fibrosus.Due toLoss of water, Protein,Mucopolysahcharide,result in loss of disc height.

Osteophyte originate from the vertebral bodies due to abnormal movement, Osteophyte extend in to spinal canal results narrowing spiral canal and cord compression.Osteophyte extend in to intervertebral disc spaceresults auto fusion of vertebral bodies.Decreased Lumbar motion and improvementof symptoms.

PATHOPHYSIOLOGY:

Intervertebral disks are believed to undergo a "degenerative cascade" of three overlapping phases.

Phase I - Dysfunction Phase

Phase II - Instability Phase

Phase III - Stabilization Phase

Phase I - Dysfunction Phase

- ✓ Seen between 15 to 45 years of age
- ✓ Circumferential and radial tear seen in the disc annulus
- ✓ Localized synovitis of the facet joints is seen

Phase II - Instability Phase

- ✓ Seen between 35 to 70 years of age
- ✓ There is internal disruption of the disc
- ✓ Progressive disc resorbtion takes place
- ✓ Degenerative of facet joint with lax capsules, subluxation and joint erosions are seen.

Phase III - Stabilization Phase

- ✓ Seen over 60 years of age
- ✓ Progressive development of hypertrophic bone above the disc and facet joints leading to segmental stiffening or frank ankylosis is seen.

EXAMINATION:

INSPECTION:

Congenital are pathological skeletal deformities like scoliosis, lordosis or kyphosis.

PALPATION:

1. TENDERNESS:

- Scatter tenderness over the low back.
- Localized tender infilterates of the skin and subcutaneous tissue
- Palpable tender induration of small intervertebral muscles
- Tenderness at the level of posterior articulation and pain on percussion of affected intervertebral space.

2. MOVEMENTS:

Movementsofthisspine :

1. Totestflexion :

Instruct the patient to bend forwards as much as possible at the waist. Normalflexion is 80 degree or fingertips 3-4 inches from the floor.

2. LateralFlexion :

Instruct the patient to bend to the left and to the right as far as possible. Normal range is 35 degree on each side.

3. Extension :

Instructs the patient to bend at waist as far backward as possible normal rangeis 20 degree – 30 degree

4. Rotation :

Instructs the patient to rotate from the waist to the left and to the right as far aspossible. Normal range is 45 degree possible.

All the movements of the spine are tested and found to be controlled in all direction.

3. CLINICALTESTS:

i. ***Straight leg raising test (SLR)***

With the patient lying supine, lift the foot to flex the hip passively with the knee kept straight. Measure the angle between the couch and the flexed leg to determine any limitations (normal 80-90 degree hip flexion). If the limit is reached, raise the leg to just less than this level and test for nerve root tension by dorsiflexing the foot.

ii. ***Braggard's test***

A SLR procedure is done if positive the leg is lowered just below the point of pain and then the ankle is dorsiflexed. If pain increases pain is likely nervous in orgin whereas with no increase the source is presumed muscules.

iii. ***Femoral nerve stretch test:***

With the patient lying on the front, flex the knee and then extend the hip .This stretches the femoral nerve. A positive result is when pain is felt in the back or the front of thigh.

iv. ***Schober'stest***

Mark the skin in midline at the level of the dimples of Venus which overlies the sacroiliac joints (mark A). Using a tape measure, draw two marks, one 10 cm above(mark B) and one 5cm belowthis(mark C)

Place the end of the tape measure on the upper mark and ask the patient to touch the toes. The distance from mark B to mark C should increase from 15 to more than 20 cm.

v. ***Forward bending to touch the toes:***

vi. ***Flip test*****:**

If a degree of functional overlay is suspected, ask the patient to sit on the end of the couch with hip and knee flexed to 90 degree.

Examine the knee reflexes and then extended the knee, as if to examine the ankle joint. The genuine sufferer will lie back, otherwise you will have effectively demonstrated a difference between the SLR test when lying and when seated.

vii.*Lassegue test:*

Inclusion of ankle dorsiflexation in the straight leg raising.

viii. *Bowstring sign:*

Rise the leg to the point where pain is experienced. Now without reducing the amount of lift, bend the knee so as to near the saiatic nerve-buttock pain is immediately relieved.

Pain may then reinduced without extending the knee by simply pressing on the lateral popliteal nerve to tighten it like a bow string.

ix. *Buckling's Sign:*

Reflexive flexion of the patient's knee during SLR.

DIAGNOSIS:

- History taking
- Physical examination
- X-ray
- MRI scan
- CT scan
- Myelogram
- Disco graphy
- Nerve conduction studies
- EMG

DIFFERENTIALDIAGNOSIS:

- Osteoporosis
- Multiple myelomas
- Multiple sclerosis
- Extra dural tumour
- Ankylosis spondylosis
- Spino vascular insufficiency
- Peripheral neuropathy
- Herpes zoster

- TB Spine
- Rheumatoid arthiritis
- SLE

COMPLICATIONS:

- Severe spinal canal stenosis
- Cauda equina syndrome
- Neurogenic claudication
- Paraplegia
- Conus Medullaris.

TESTS AND ASSESMENTS:

- Clinical assessment
- Siddha assessment
- Laboratory Investigations
- Radiological assessment

CLINICAL ASSESSMENT:

- Pain in lumbar region
- Radiating pain to buttocks and lower limbs
- Diffuse tenderness in lumbar region with limitation of movements
- Stiffness of lumbar spine
- Exacerbation of pain on movements
- Pain increased on forward bending
- Paraesthesia& sensory loss on affected area
- Burning and tingling sensation in lower limbs

PAIN ASSESMENT:

Improvement assessed by following assessments:

1. Pain assessment scale (17)
2. Restricted movement assessment scale

RESTRICTED MOVEMENT ASSESSMENT SCALE:

GRADATION OF MOVEMENTS:

Grade 1 **:** Fit for all activities to do their work without support (Normal)

Grade 2 **:** Mild pain and mild restriction of movements.

Grade 3 **:** Moderate Pain with or without radiation to lower limbs and moderate restriction of Movements

Grade 4 **:** Severe Pain with or without radiation to lower limbs and Severe restriction of Movements

SIDDHA ASSESMENT:

EnvagaiThervu:

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram
    - Neerkkuri
    - Neikkuri

LABORATORY INVESTIGATIONS:

Blood:

- TC
- DC
- ESR
- Hb
- Blood Sugar

    Fasting

    Post prandial

- Blood urea
- Serum Creatinine
- Serum Cholesterol

Urine:

- Albumin
- Sugar
- Deposits

SPECIFIC INVESTIGATIONS:

SEROLOGY:

- CRP
- RA factor
- ASO titre

RADIOLOGICAL INVESTIGATION:

- X- Ray: Lumbar spine AP and lateral view
- MRI (If required)

Diagnosis:

The diagnosis was made by following Siddha diagnostic methods. Nilam, Kaalam, Poriyalaridhal, Pulanalarithal, Vinaadhal, Mukkutra Nilaigal, Udal Thathukal Nilai and Envagai Thervugal, and the diagnosis of Thandaga Vadham were obtained which correlated with modern diagnosis of lumbar Spondylosis by the X-Ray findings.

THE BACK PAIN FUNCTION SCALE (BPFS) OF STRATFORD ET

Stratford et al developed the back pain function scale (BPFS) to evaluation functional ability in patients with back pain. The authors are from McMaster University Appalachian physical theraphy (Georgia) and Virginia common wealth university.

Measure :

1. Any of your usual work housework or school activities
2. Your usual hobbies recreational or sporting activities
3. Performing heavy activities around your home.

4. Bending or stooping
5. Putting your shoes or socks (or stockings or pantyhose)
6. Lifting a box of groceries from the floor
7. Sleeping
8. Standing for 1 hour
9. Walking 1 mile
10. Going up or down 2 flights of stairs (about 20 steps)
11. Sitting for 1 hour
12. Driving for 1 hour

Responses	**Points**
Unable to perform activity	0
Extreme difficulty	1
Quite a bit of difficulty	2
Moderate difficulty	3
A little bit of difficulty	4
No difficulty	5

Total score = sum (points for all 12 measure)

Adjusted total score = total score / 60

Interpretation:

- Minimum score : 0
- Maximum score : 60
- Maximum adjusted score : 1
- The higher the score the greater the patient's functional ability.

TREATMENT:

Vellai ennai 15ml at morning with hot water was given on the first day of treatment.All the patients were treated with the following medicines.

1. KUSTATHI CHOORNAM – 1 gram thrice a day with hot water
2. ERANDA THYLAM – 30 ml applied externally

Varmam is applied as the complementary therapy for inpatients.

RESULTS AND OBSERVATION

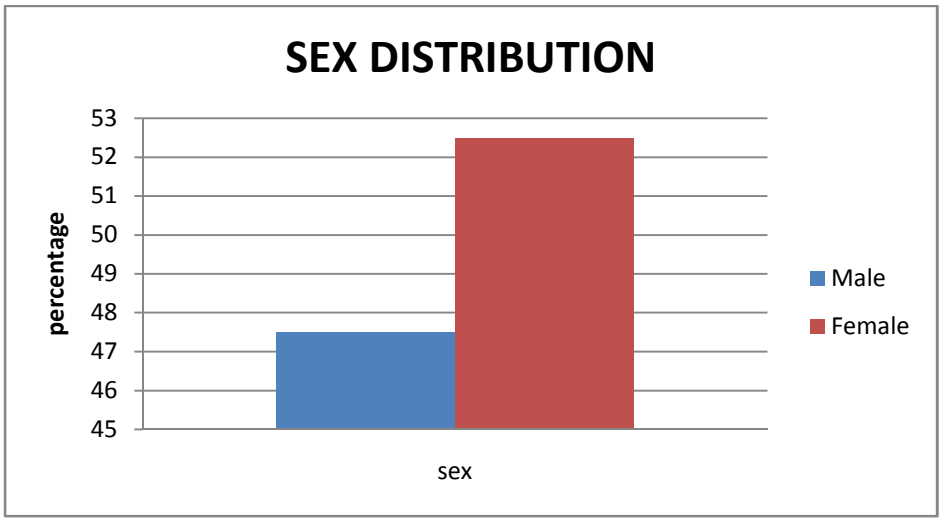
For the clinical study 40 patients were selected and treated in PG-III Sirappu Maruthuvam Department, GSMC hospital Palayamkottai. Results were observed with respect to the following criteria.

1. Sex
2. Age
3. Kalam
4. Thega nilai
5. Gunam
6. Thinai
7. Paruvakalam
8. Socio-Economic Status
9. Etiological Factors
10. Occupation
11. Clinical Presentation
12. Duration of Illness
13. Mukkutram
14. Udal Thathukkal
15. Envagai Thervugal
16. Pulse Reading
17. Neikkuri
18. Provocative Test
19. Number of Days Treated
20. Laboratory Investigations
21. Radiological Findings
22. Pain scale Readings
23. Effect of Varmam
24. Over all curative effect.

1. Sex distribution

Table 1: Illustrates sex distributions and its relative percentage

Sex	OP Cases	IP Cases	TOTAL
Male	11	8	19
Female	9	12	21
TOTAL	20	20	40



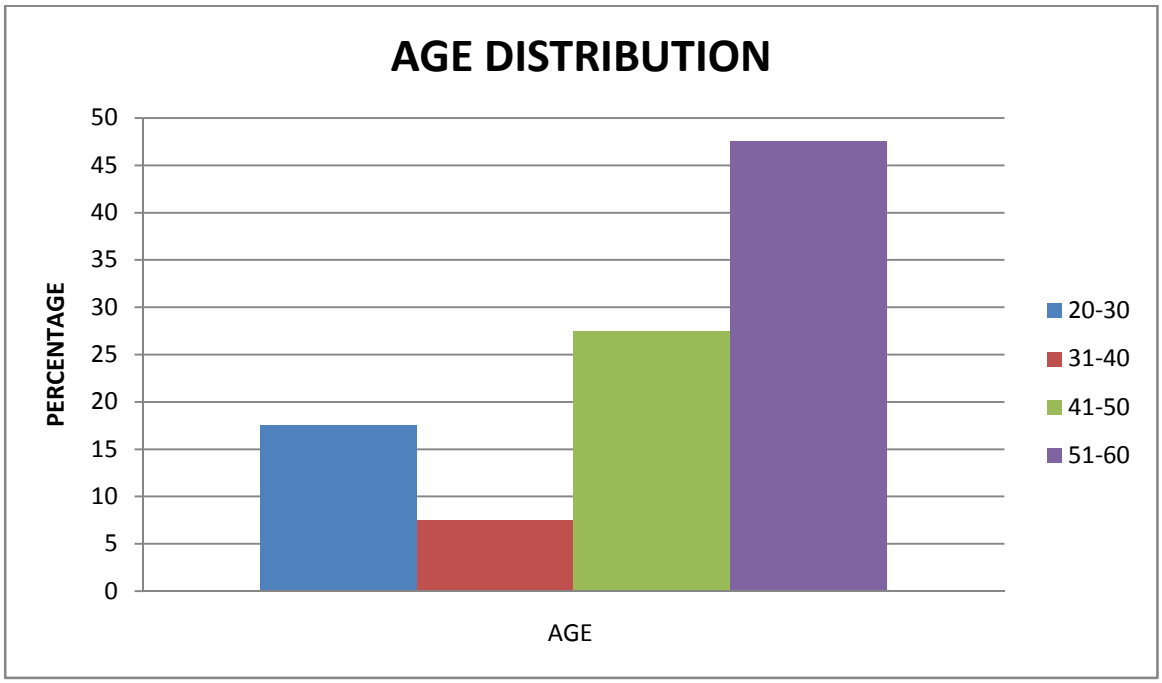
INFERENCE:

Out of 40 in patients, 47.5% were males and 52.5% were females.

2. Age distribution

Table 2: Illustrates the age distributions.

AGE GROUP	NO.OF.PATIENT	PERCENTAGE(%)
20-30	7	17.5
31-40	3	7.5
41-50	11	27.5
51-60	19	47.5



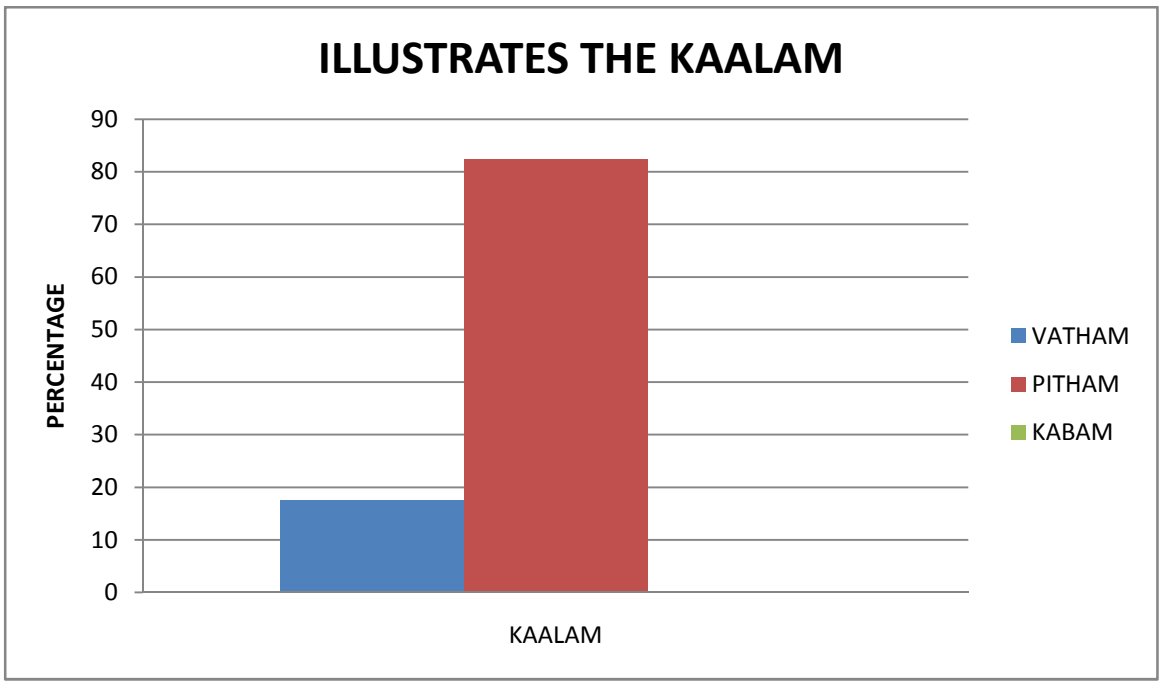
INFERENCE::

Among the 40 patients, in the highest incidence was in the age between 51-60 lowest incidence was in the age between 31-40.

3. Kalam:

Table 3: Illustrates the kalam

S. No	Kalam	Patients	
		No of cases	Percentage
1.	Vadha Kalam(11-33YRS)	7	17.5
2.	Pitha Kalam(34-66YRS)	33	82.5
3.	Kabha Kalam(67-70YRS)	-	-



INFERENCE :

Out of 40 Patients,

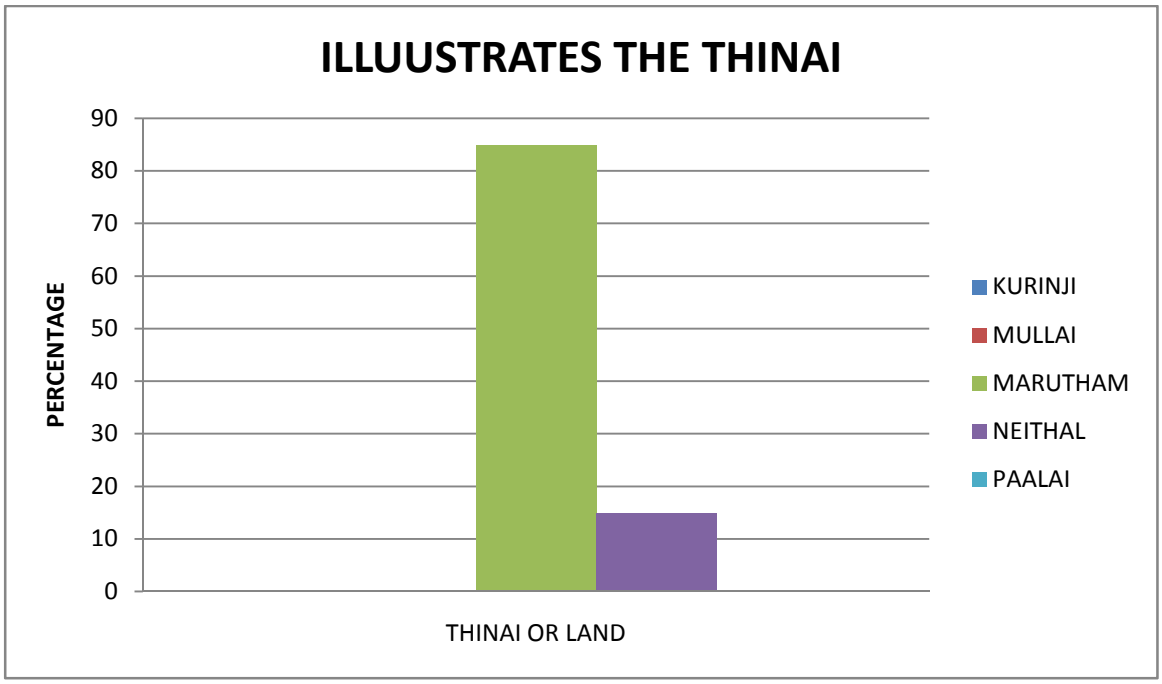
* 17.5% of cases were in the Vadha kalam

* 82.5% of cases were in the Pitha kalam.

4.Thinai (The habitat of the patients)

Table 4: Illustrates the Thinai

S. No	Thinai	OP & IP Patients	
		No. of cases	Percentage
1.	Kurinji	-	-
2.	Mullai	-	-
3.	Marutham	34	85
4.	Neithal	6	15
5.	Palai	-	-



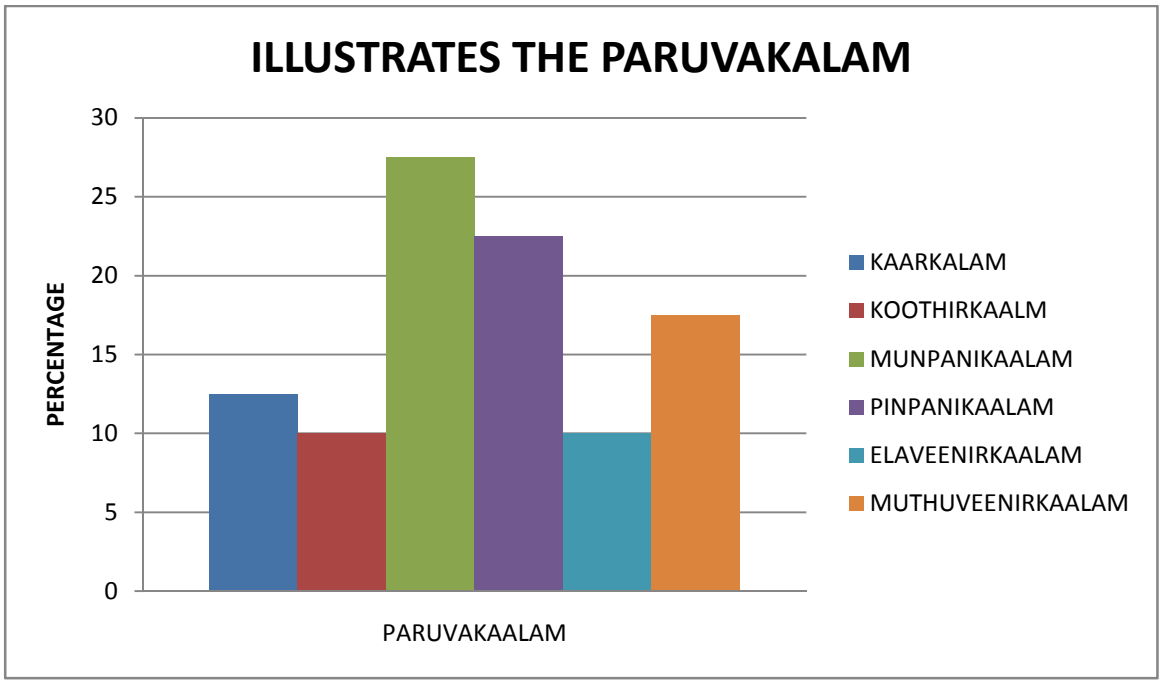
INFERENCE:

85 % of the patients were from Marutha nilam and 15% were from neithal.

5. Paruva kalam

Table 5: Illustrates the paruva kalam and its relative percentage:

S. No.	Paruva Kalam	Months	No. of Cases	Percentages
1.	Kar kalam	Aavani, Purattasi(Aug.15 to Oct14)	5	12.5
2.	Koothir kalam	Iyppasi, Karthigai(Oct.15 to Dec.14)	4	10
3.	Munpani Kalam	Markazhi, Thai(Dec.15 to Feb.14)	11	27.5
4.	Pinpani Kalam	Masi, Panguni(Feb.15 to Apr.14)	9	22.5
5.	Elavenil Kalam	Chithirai, Vaikasi(Apr.15 to June.14)	4	10
6.	Muthuvenil Kalam	Aani, Aadi(June 15 to Aug.14)	7	17.5



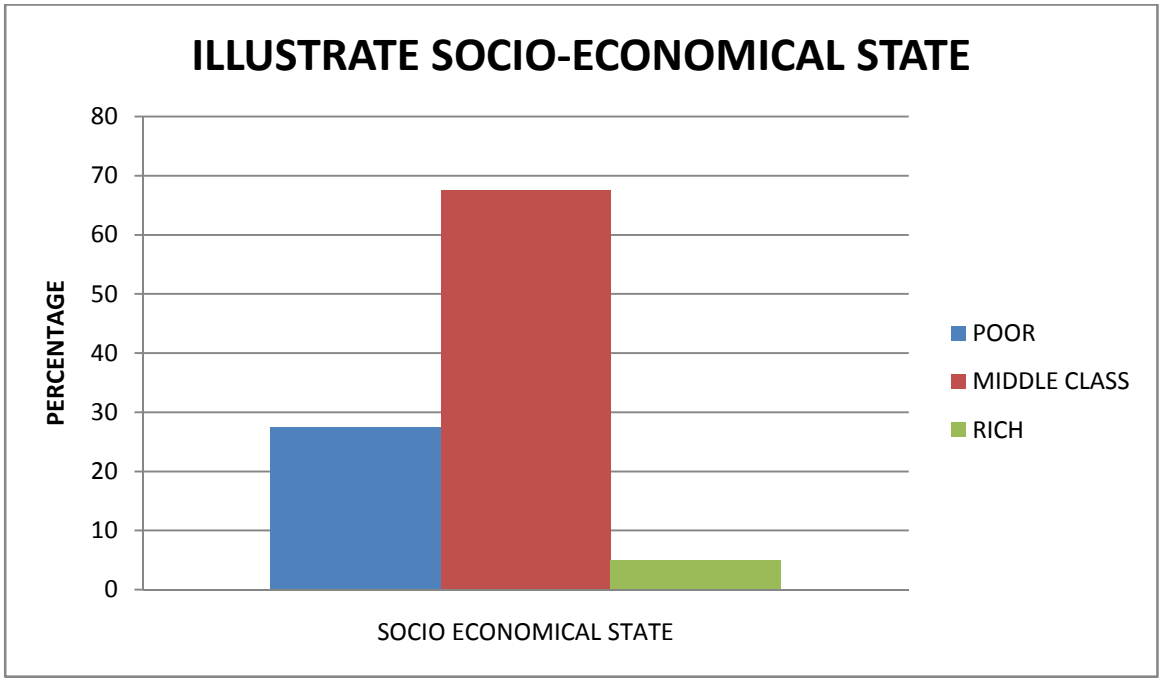
INFERENCE:

Out of 40 patients,27.5% were come in munpanikalam,22.5% in pinpanikalam,17.5% in mudhuvenilkalam,12.5% came in karkalam and each 10% came in koothirkalam and elavenilkalam.

6.Socio – Economic status

Table 6: Illustrates the socio-economic status

S. No	Socio-economic Status	No. of cases	Percentage
1.	Rich	2	5
2.	Middle class	27	67.5
3.	Poor	11	27.5



INFERENCE:

Out of 40 patients,

67.5 % are middle class

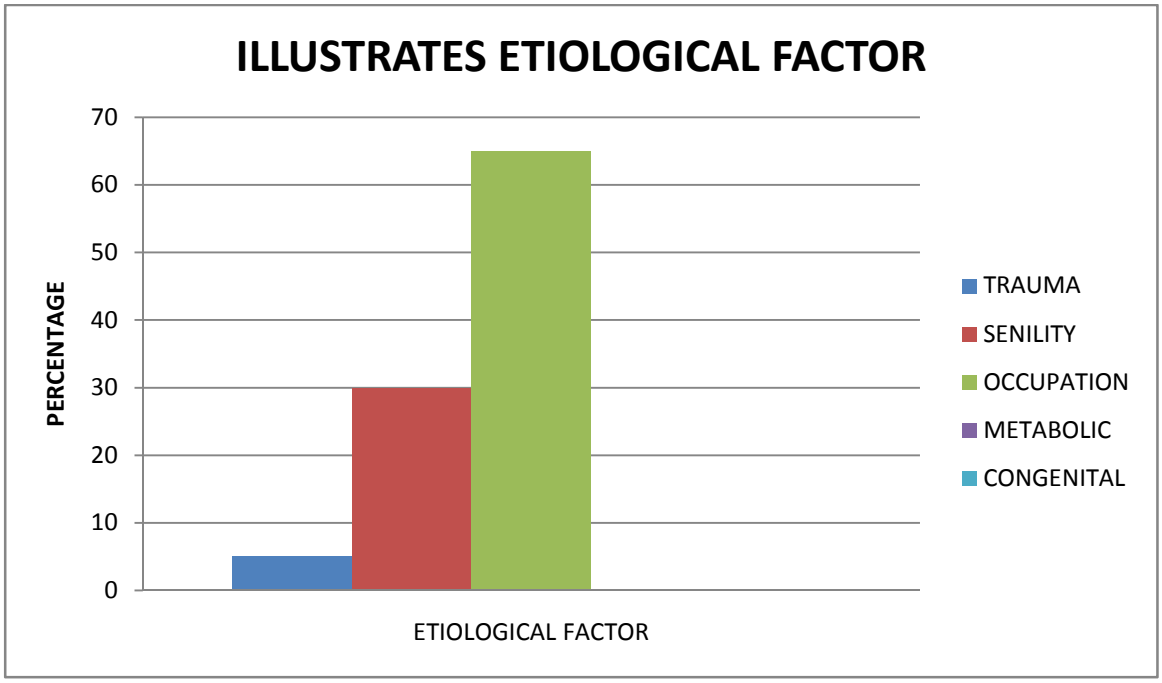
27.5% are poor

5% are rich

7. Distribution based on Etiological factors:

Table 7: Illustrates etiological factors

S. No.	Precipitating Factors	No. of cases	Percentage
1.	Senility	12	30
2.	Occupation	26	65
3.	Trauma	2	5
4.	Metabolic	-	-
5.	Congenital	-	-



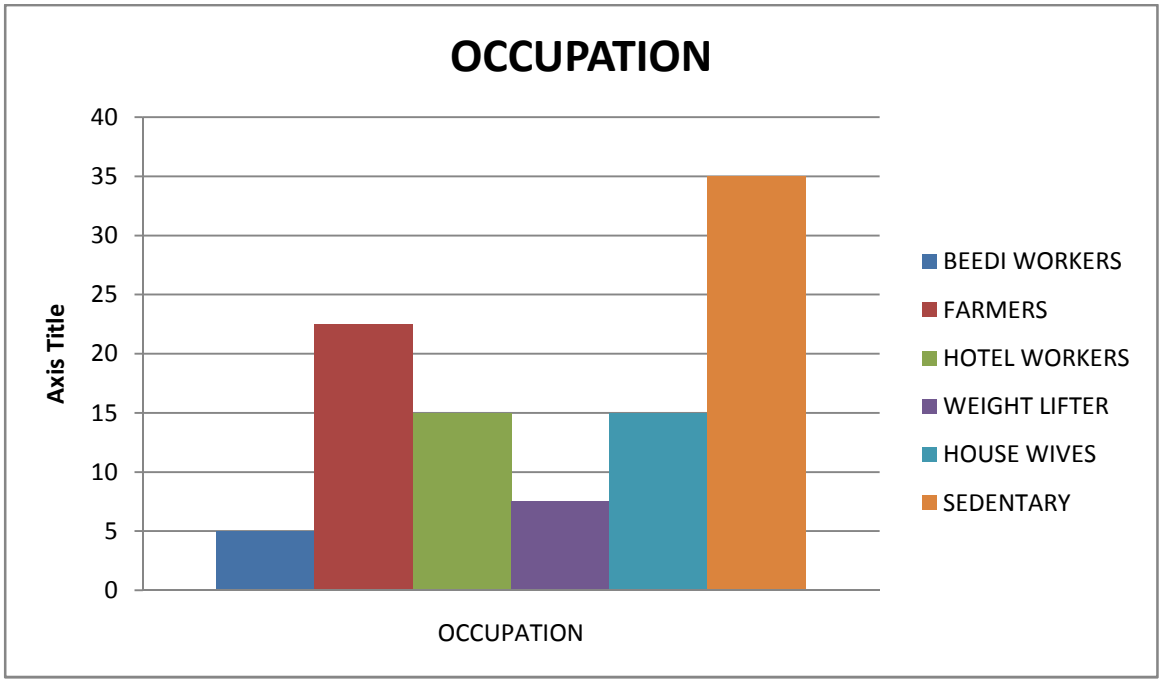
INFERENCE:

Out of 40 patients, 65% of thandagavatham are caused due to occupational cause and remaining 30% and 5% are caused due to senility and trauma respectively.

8. Occupation:

Table 8: Illustrates occupation

S.NO	**OCCUPATION**	**NO.OF.PATIENTS**	**PERCENTAGE(%)**
1.	Beediworkers	2	5
2.	Farmers	9	22.5
3.	Sedentary	6	15
4.	Hotel workers	3	7.5
5	Weight lifters	6	15
6	House wives	14	35



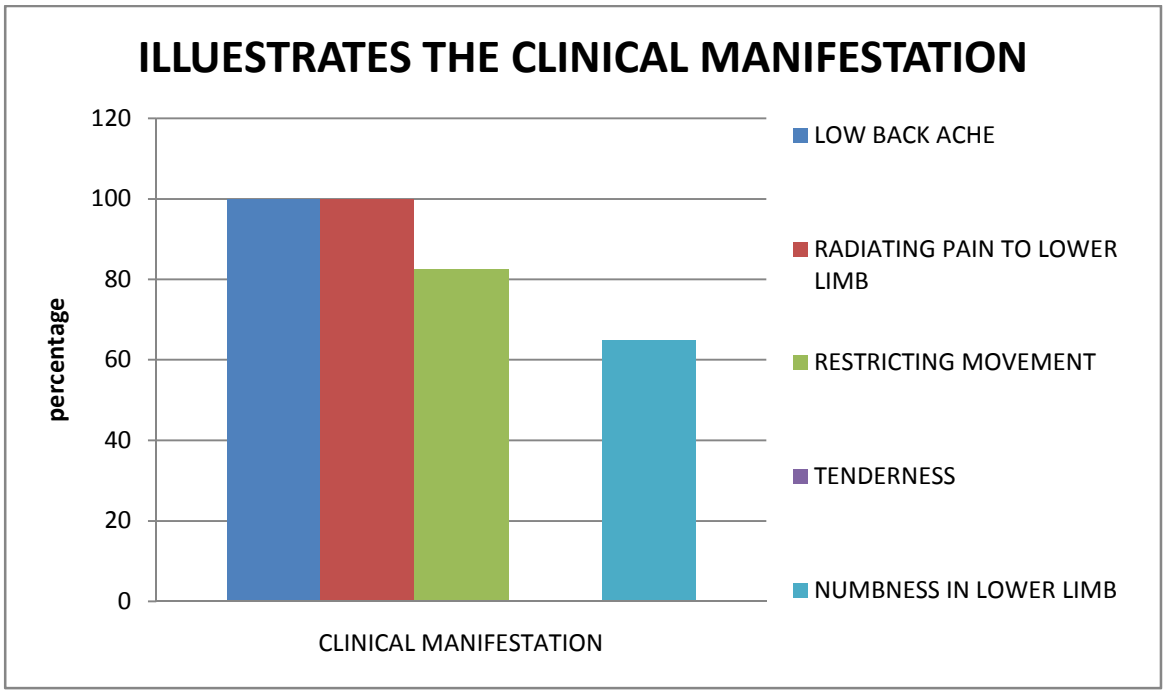
INFERENCE:

35% were housewives and 22.5 % were farmers,each 15 were from sedentary and weight lifters respectively and 7.5% from hotel workers.

9. Clinical Manifestations:

Table9: Illustrates the Clinical Manifestations

Sl.no	Signs and symptoms	No. of cases	Percentage
1.	Low back ache	40	100
2.	Radiating pain to lower limbs	40	100
3.	Restricted movements	33	82.5
4.	Tenderness	-	-
5.	Numbness in lower limbs	26	65



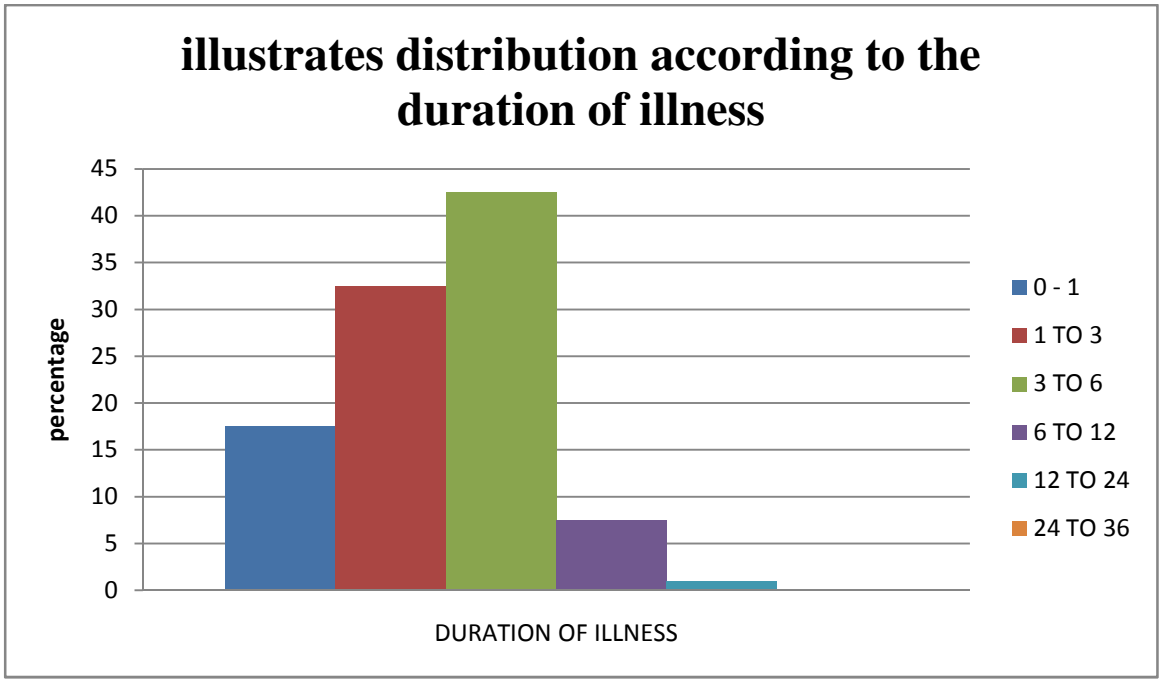
INFERENCE:

100% people have low back ache and radiating pain, 82.5% have restricted movements, 65% have numbness in the lower limbs.

10. Distribution According to the duration of illness:

Table 10: Illustrate the duration of illness with their respective percentage:

S. No.	Duration of illness (Months)	No. of cases	Percentage
1.	0-1	7	17.5
2.	1-3	13	32.5
3.	3-6	17	42.5
4.	6-12	3	7.5
5.	12-24	-	-
6.	24-36	-	-



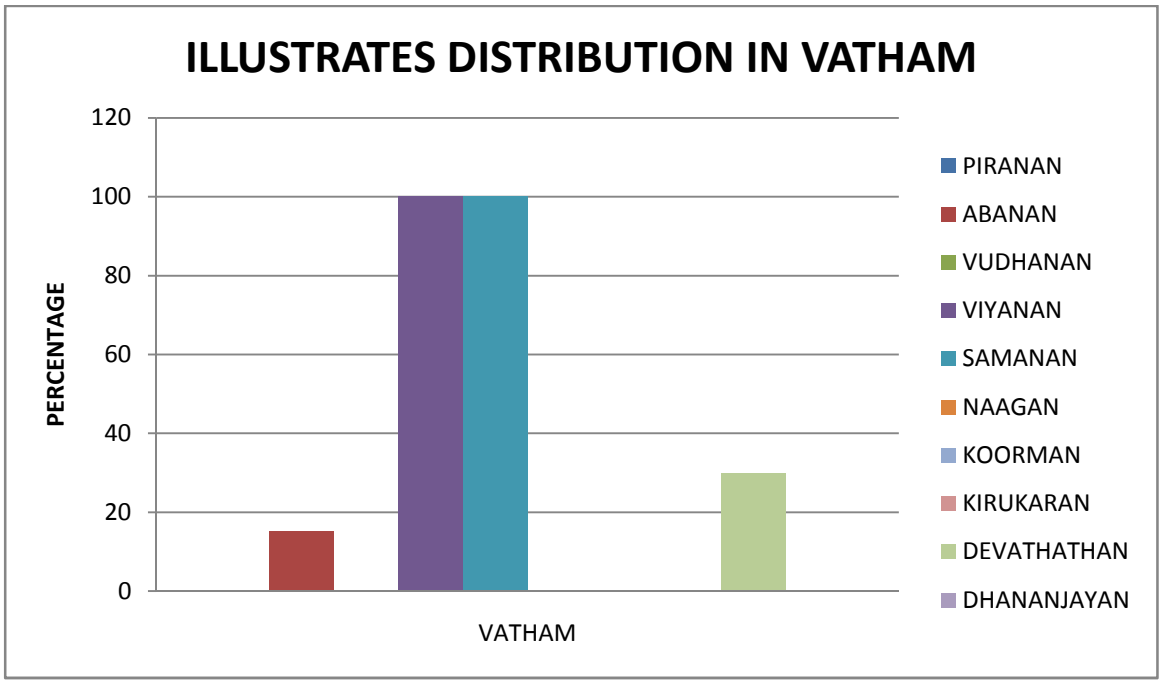
INFERENCE:

In 40 patients, 42.5% have 3-6 month duration of pain , 32.5% have 1-3 month of pain,17.5% have 1 month duration of pain and 7.5% have 6-12 month duration of pain.

10. Conditions of Mukkuttram

a. Disturbance in Vadha:

S. No.	Disturbance In Vadha	No of cases	Percentage
1.	Piranan	-	-
2.	Abanan	6	15
3.	Viyanan	40	100
4.	Udhanan	-	-
5.	Samanan	40	100
6.	Nagan	-	-
7.	Koorman	-	-
8.	Kirukaran	-	-
9.	Dhevathathan	20	50
10.	Dhananjeyan	-	-

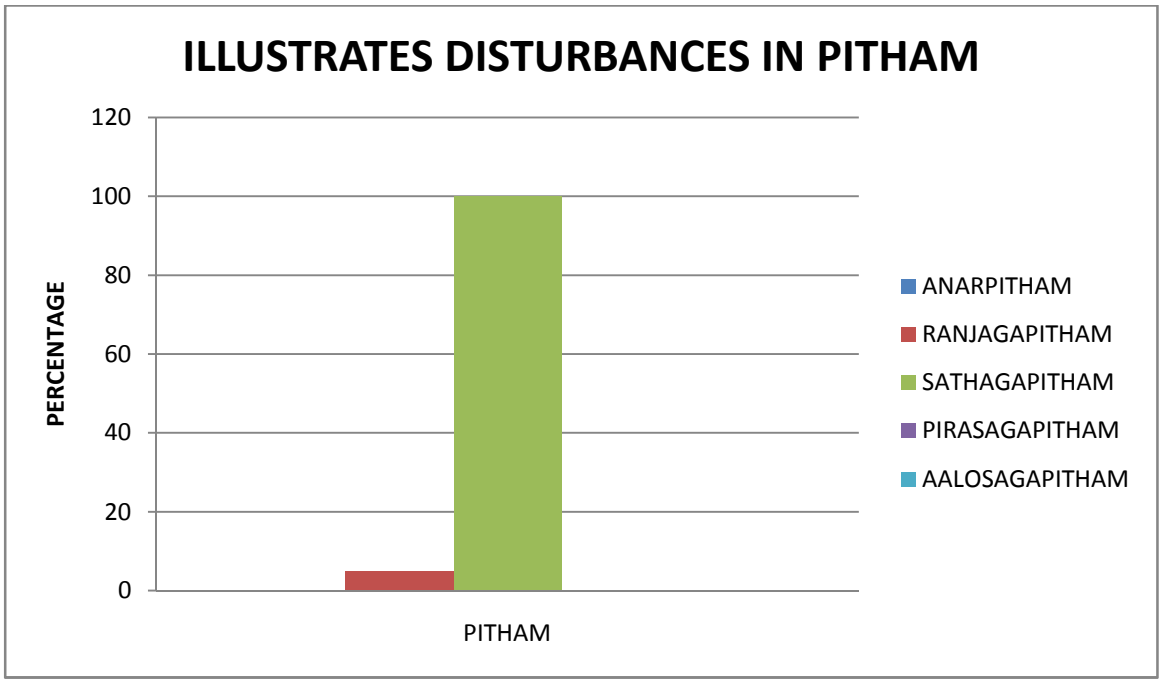


INFERENCE:

viyanan and samanan were affected in 100% of cases, devathathan affected in 50% of cases

b. Disturbances in Pitha:

S. No.	Disturbances in Pitha	No of cases	Percentage
1.	Anar Pitham	-	-
2.	Ranjagam	5	12.5
3.	Prasagam	-	-
4.	Alosagam	-	-
5.	Sathagam	40	100

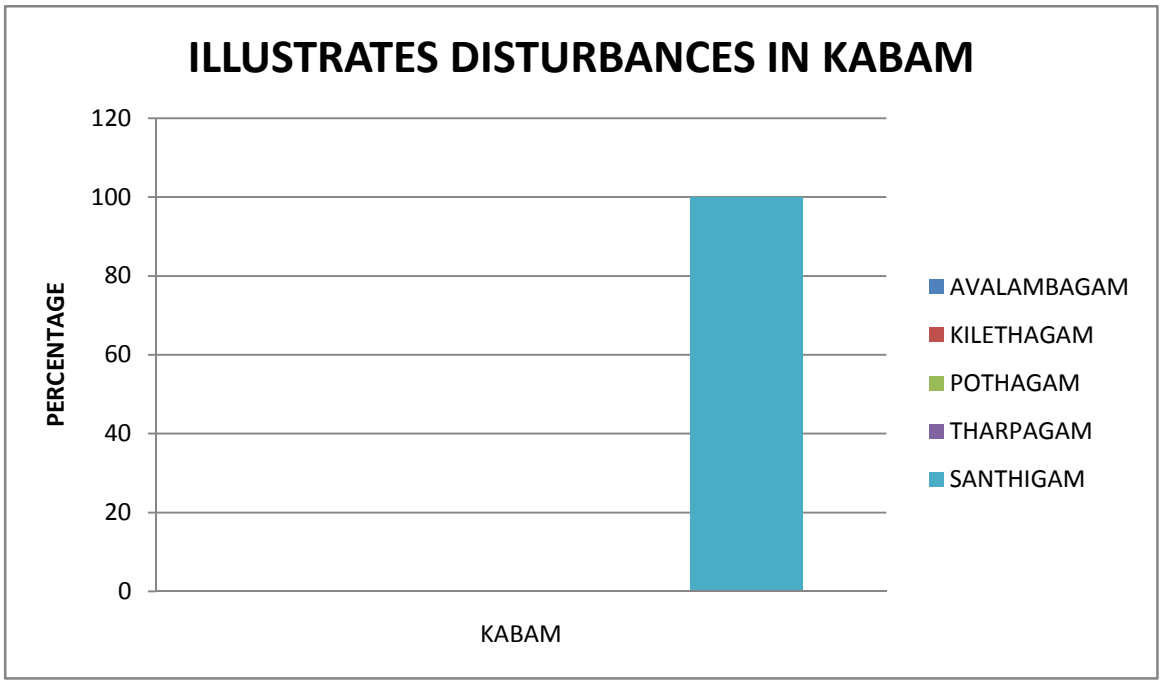


INFERENCE:

Sathaga pitham was altered in all cases (100%) evidenced as difficulty in handling their regular duties because of pain in lumbar region & lower limb. Ranjaga pitham was affected in 12.5% patients having decreased RBC.

c. Disturbances in Kabha:

S. No.	Disturbances in Kabha	No. of cases	Percentage
1.	Avalambagam	0	0
2.	Kilethagam	-	-
3.	Bothagam	-	-
4.	Tharpagam	-	-
5.	Santhigam	40	100

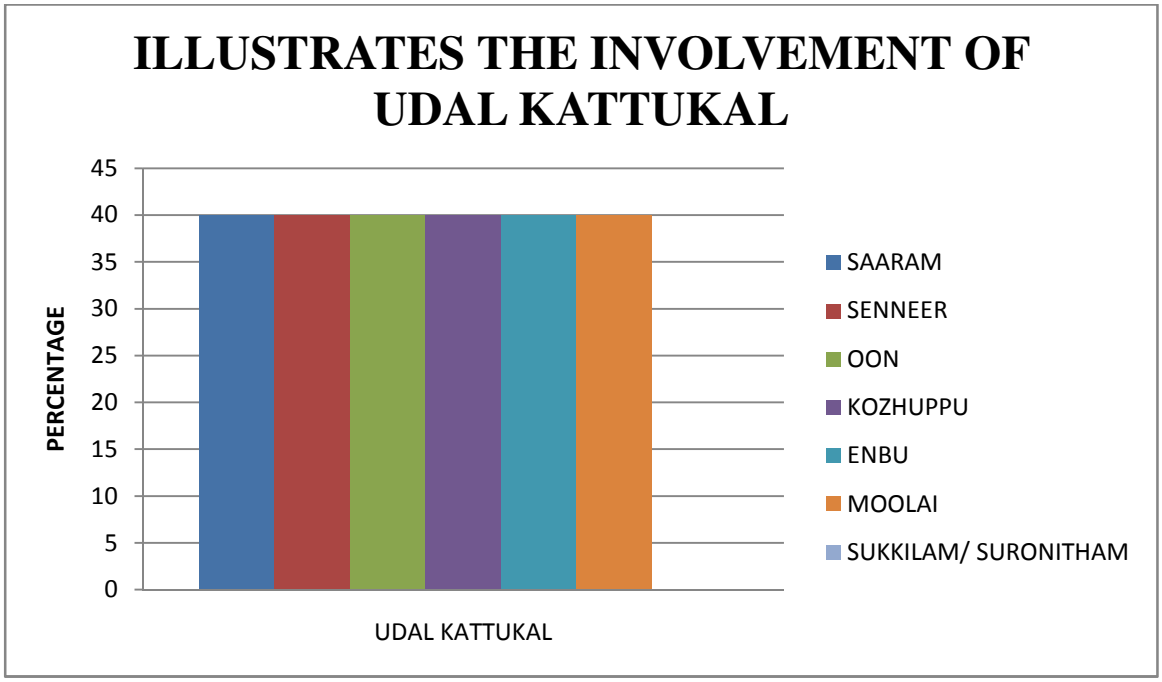


INFERENCE:

Santhigam was found to be affected in all 40 cases (100%)

11. Involvement of Udal Thathukkal

S. No.	Udal Thathukkal	No of cases affected	Percentage
1.	Saram	40	100
2.	Senneer	40	100
3.	Oon	40	100
4.	Kozhuppu	40	100
5.	Enbu	40	100
6.	Moolai	40	100
7.	Sukkilam / Suronitham	0	0

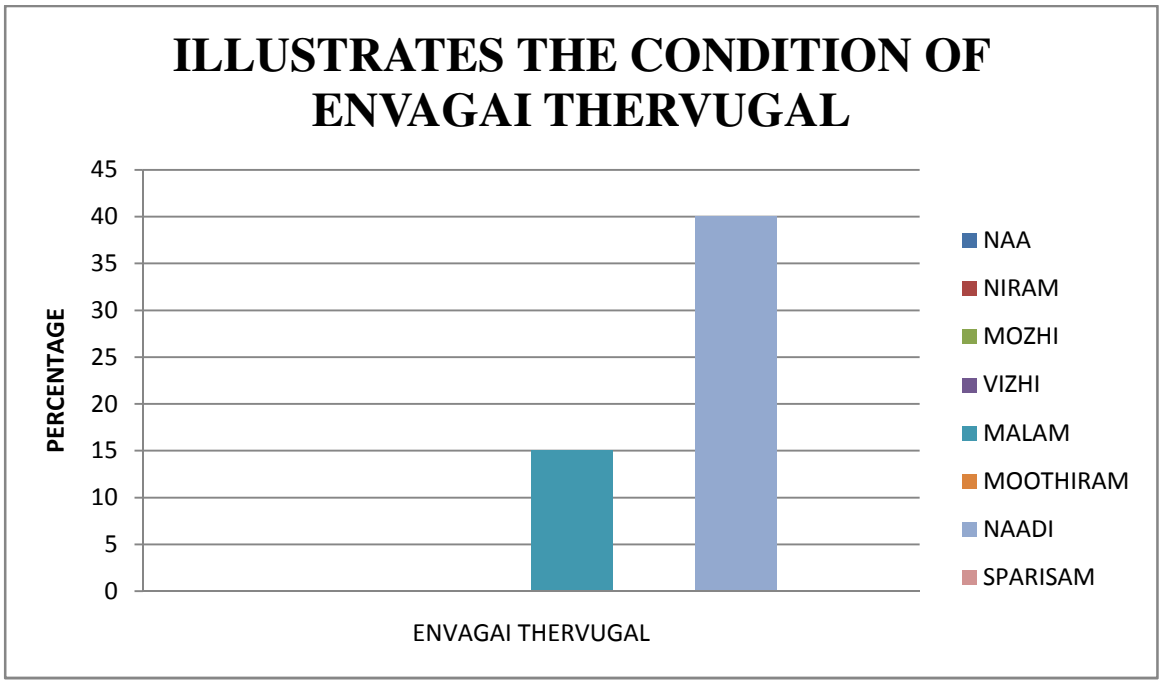


INFERENCE:

All the udal thathukkal were affected 100% in thandagavadham cases.

12. Condition of Envagai Thervugal

S. No.	En vagai thervu	No of cases	Percentage
1.	Naa	-	-
2.	Niram	-	-
3.	Mozhi	-	-
4.	Vizhi	-	-
5.	Malam	6	15
6.	Moothiram	-	-
7.	Sparisam	-	-
8.	Naadi (Thontha naadi)	40	100



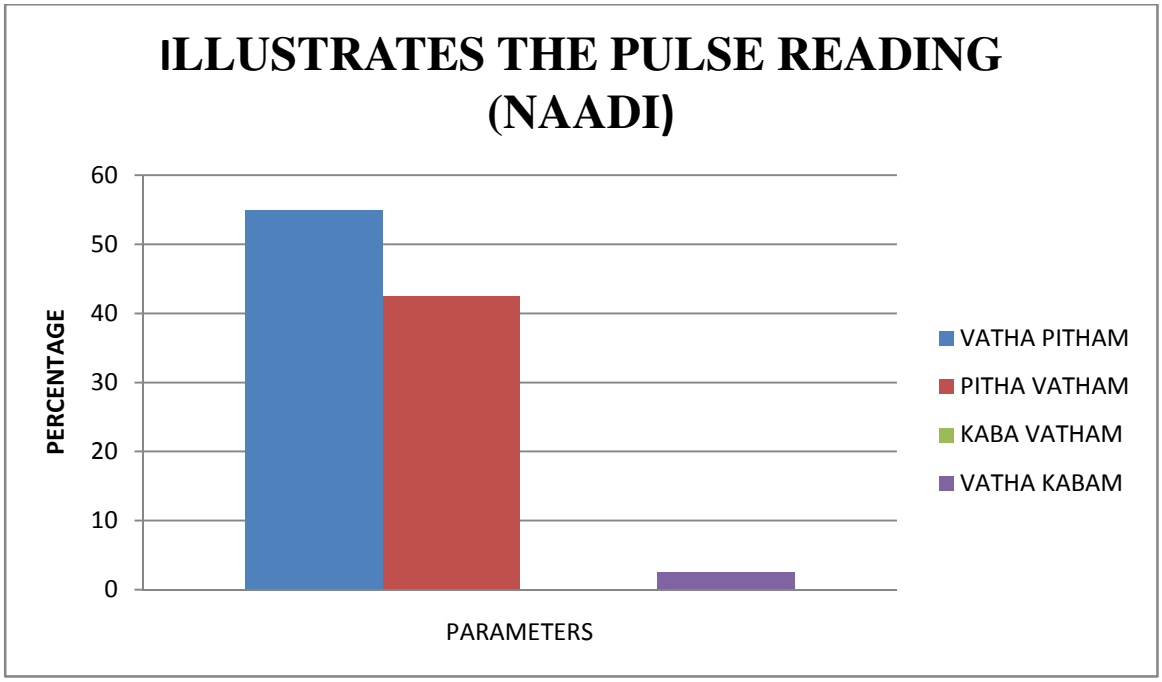
INFERENCE:

15% were affected with the condition of malam and 100% affected with thontha naadi.

13. Naadi:

Table 13:Illustrate for the pulse parameters:

S. No.	Parameters	No. of cases	Percentage
1.	Vatha pitham	22	55
2.	Pitha vatham	17	42.5
3.	Kaba vatham	-	-
4.	Vatha kabam	1	2.5

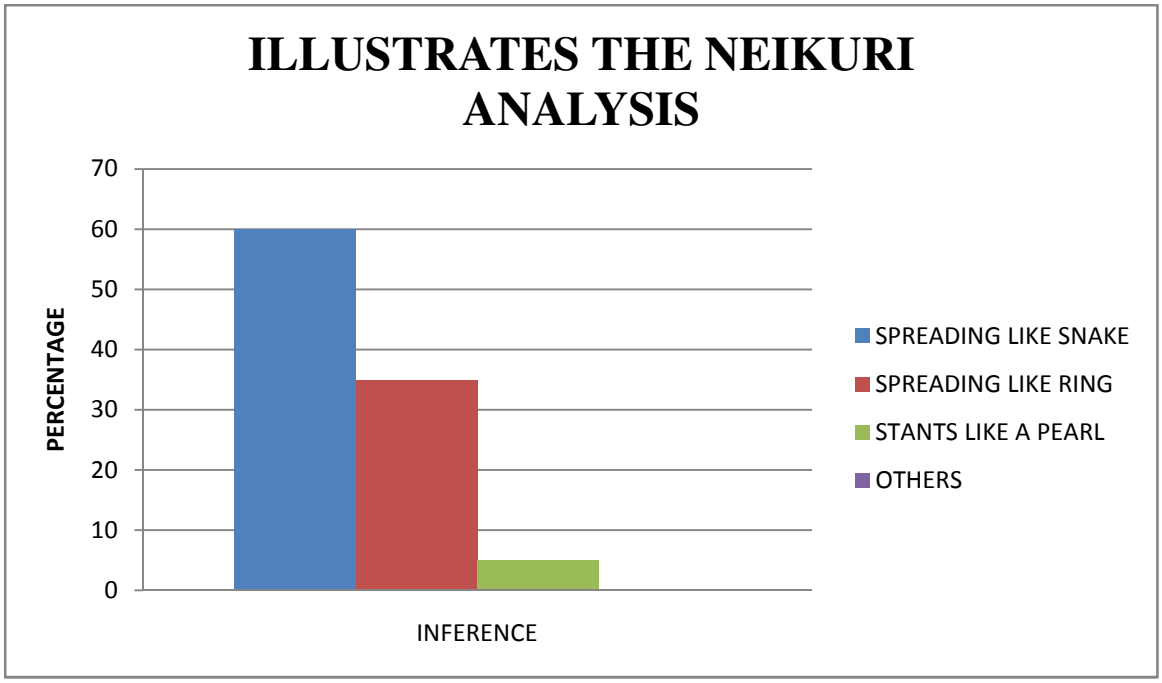


INFERENCE:

Most of the cases were affected with 55% vathapitha naadi,42.5% were affected with pithavatha naadi and only 2.5% were affected with vathakabha naadi.

14. Neikuri:

S. No.	Inference	No. of cases	Percentage
1.	Spreading like snake	24	65
2.	Spreading like a ring	14	35
3.	Stands like a pearl	2	5
4.	Combination of ring and snake	-	-

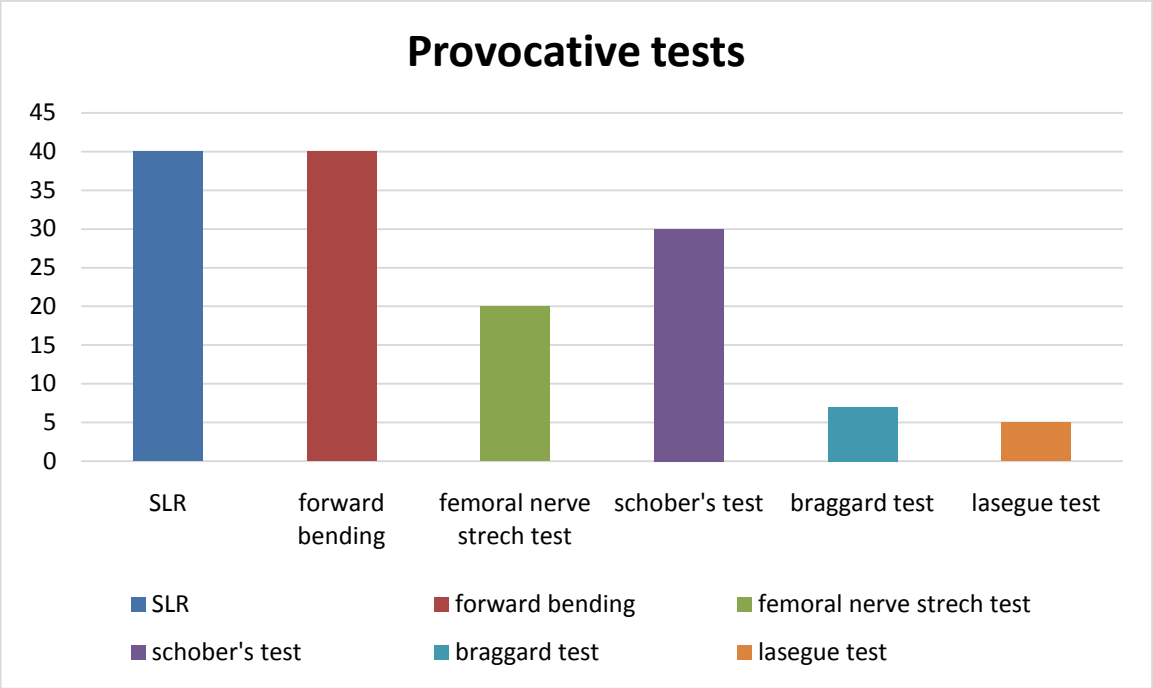


INFERENCE:

60% Patients having vatha neer which spreads like a snake,35% having pitha neer which spreads like a ring and 55 having kaba neer which soreads like a pearl.

14. Provocative test:

S. No.	Clinical features	No. of cases Positive	Percentage
1	SLR	40	100
2	Forward bending	40	100
3	Femoral nerve stretch test	20	50
4	Schober's test	30	75
5	Braggard test	7	17.5
6	Lasegue test	5	12.5



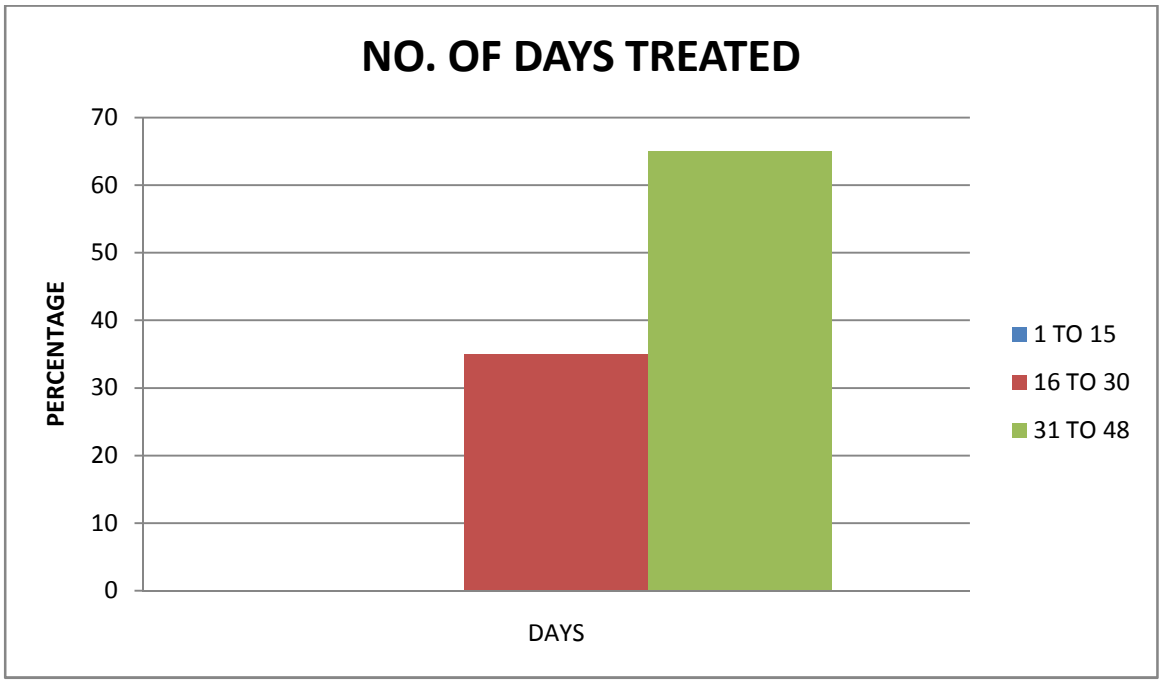
INFERENCE:

Based on modern aspect for the diagnostic purpose,provocative studies were done.In that SLR and foeward bending were affected 100%,50% femoral nerve test,75% schobler's test were positive.

15.. No. of days treatment:

Table 15: Distribution According to the total number of days for treatment:

S.No	No. of days treatment	No. of cases	Percentage
		Op,ip	%
1	1–15	-	-
2	15-30	14	35
3	31-48	26	65



INFERENCE:

Out of 40 patients,65% patients were treated 31-48ndays and 35% patients were treated 16-30 days.

16. Observations of other Clinical Laboratory Examinations:

At the time of admission and discharge routine laboratory examination were done and values were record

s.no.	OP No.	TC(cells/cumm)		DC(%)						ESR(mm)		Hb(gms%)		SUG.		ALB.		DEP.	
		BT	AT	BT			AT			BT 1 hr	AT 1hr	BT	AT	BT	AT	BT	AT	BT	AT
1	63877	7800	7900	64	29	7	66	31	3	18	14	11.4	11,6	Nil	Nil	Nil	Nil	NAD	NAD
2	65820	8200	8400	70	22	8	72	21	6	5	3	13	13.2	Nil	Nil	Nil	Nil	NAD	NAD
3	70870	7100	7400	64	32	4	65	31	2	8	6	12.1	12.4	Nil	Nil	Nil	Nil	NAD	1 – 2 pus cells
4	72235	8900	8900	77	20	3	55	40	5	58	42	12.8	12.9	Nil	Nil	Nil	Nil	NAD	NAD
5	73846	6900	7100	64	33	8	65	33	2	14	12	12.6	12.7	Nil	Nil	Nil	Nil	NAD	NAD
6	74998	7600	7800	50	46	1	55	43	2	20	14	11.3	11.6	Nil	Nil	Nil	Nil	NAD	NAD
7	75064	7200	7300	53	40	7	67	27	6	4	2	16.5	16.2	Nil	Nil	Nil	Nil	NAD	NAD
8	81407	7600	7800	63	34	3	64	36	3	14	8	11.6	11.8	.Nil	Nil	Nil	Nil	NAD	NAD
9	111084	8100	8400	61	33	6	64	34	2	11	8	12.4	12.6	Nil	Nil	Nil	Nil	NAD	NAD
10	111088	7310	7700	61	34	5	64	33	1	12	8	10.6	10.9	Nil	Nil	Nil	Nil	NAD	NAD
11	112021	7500	7700	59	34	7	61	36	4	11	9	12.6	12.7	Nil	Nil	Nil	Nil	NAD	NAD
12	111983	9500	9700	70	22	8	71	24	5	6	4	10.9	11.1	Nil	Nil	Nil	Nil	NAD	NAD
13	112279	7200	7500	57	34	7	61	34	5	14	10	10.1	10.3	Nil	Nil	Nil	Nil	NAD	NAD
14	113753	6300	6900	63	34	3	58	38	4	5	5	11	11	Nil	Nil	Nil	Nil	NAD	NAD
15	114078	7200	7400	61	34	5	63	36	1	12	9	12,6	12.8	Nil	Nil	Nil	Nil	NAD	NAD
16	114372	7100	7100	63	33	4	62	32	6	8	8	10.4	11.2	Nil	Nil	Nil	Nil	3 – 4 pus cells	NAD
17	17	348	7100	6500	68	28	4	50	46	4	14	12.3	12	Nil	Nil	Nil	Nil	NAD	NAD
18	297	8500	8700	70	25	5	72	24	4	10	8	12	12.2	Nil	Nil	Nil	Nil	NAD	NAD
19	991	8500	6800	53	43	4	63	34	3	6	5	12.4	12.6	Nil	Nil	Nil	Nil	NAD	NAD
20	2398	6600	7000	50	49	1	55	44	1	68	36	10.9	11.2	Nil	Nil	Nil	Nil	NAD	NAD

SL.NO.	OP No.	SUG(mgs%)		UREA(mgs%)		CHOLESTEROL (mgs%)	
		BT	AT	BT	AT	BT	AT
1	63877	85	83	17	16	148	145
2	65820	92	90	50	43	191	185
3	70870	94	93	29	26	176	170
4	72235	128	88	27	25	195	160
5	73846	90	88	31	29	168	165
6	74998	103	99	27	24	169	165
7	75064	102	97	21	18	176	159
8	81407	97	95	34	33	158	154
9	111084	93	91	29	25	164	159
10	111088	96	93	27	24	152	150
11	112021	97	95	29	26	178	173
12	111983	96	93	26	24	120	117
13	112279	92	90	27	24	138	135
14	113753	76	76	19	15	144	130
15	114078	89	80	25	23	159	154
16	114372	88	101	21	19	152	112
17	348	135	145	21	18	168	142
18	297	95	94	26	23	154	150
19	991	99	94	29	28	187	168
20	2398	107	99	29	23	208	198

		HEMATOLOGICAL STUDIES												URINE ANALYSIS					
s.no	IP No.	TC(cells/cumm)		DC(%)						ESR(mm)		Hb(gms%)		SUG.		ALB.		DEP.	
		BT	AT	BT			AT			BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	2174	7000	7100	64	32	4	61	38	1	10	11	9.3	10.1	Nil	Nil	Nil	Nil	NAD	NAD
2	3194	7300	7200	67	27	6	63	34	6	9	8	12.4	12.8	Nil	Nil	Nil	Nil	NAD	NAD
3	3251	7500	7900	61	36	3	63	36	1	13	9	11.8	12	Nil	Nil	Nil	Nil	1-2 pus cells	NAD
4	3246	8600	8650	62	30	8	61	32	7	30	26	10.7	11	Nil	Nil	Nil	Nil	NAD	NAD
5	3244	7600	7400	62	35	3	67	30	3	25	16	13.3	13.9	Nil	Nil	Nil	Nil	NAD	NAD
6	3314	7000	7200	60	32	3	66	30	2	22	17	10.4	10.8	Nil	Nil	Nil	Nil	NAD	NAD
7	34	11200	10000	63	32	5	80	16	3	50	40	12.3	12.6	Nil	Nil	Nil	Nil	NAD	NAD
8	56	7000	7300	65	33	2	64	34	2	70	55	8.4	8.9	Nil	Nil	Nil	Nil	NAD	NAD
9	83	7300	7500	58	36	6	59	34	7	18	14	11.2	11.5	Nil	Nil	Nil	Nil	NAD	NAD
10	101	9400	9900	72	15	3	71	16	3	27	21	9.6	9.9	Nil	Nil	Nil	Nil	NAD	NAD
11	136	7000	7300	54	44	2	54	45	1	28	19	7.2	7.9	Nil	Nil	Nil	Nil	NAD	NAD
12	168	10000	8300	70	26	4	53	38	9	60	70	11.2	10.9	Nil	Nil	Nil	Nil	NAD	NAD
13	190	6900	7000	61	34	5	62	35	3	11	7	12.1	12.3	Nil	Nil	Nil	Nil	NAD	NAD
14	253	7900	8500	78	20	2	66	30	4	6	8	10.0	11.1	Nil	Nil	Nil	Nil	NAD	NAD
15	309	7600	8100	60	36	4	58	38	4	15	14	11.5	11.8	Nil	Nil	Nil	Nil	3 -4 pus cells	NAD
16	587	7000	7100	54	44	2	52	43	5	63	34	9.0	9.2	Nil	Nil	Nil	Nil	NAD	NAD
17	836	7200	7400	61	33	6	62	34	4	17	11	11.2	11.5	Nil	Nil	Nil	Nil	NAD	NAD
18	837	8200	8500	74	18	8	73	21	6	13	9	13.0	9.0	Nil	Nil	Nil	Nil	NAD	NAD
19	865	13600	13600	65	33	2	66	333	1	30	15	12.1	12.3	Nil	Nil	Nil	Nil	NAD	NAD
20	932	7100	7500	51	46	3	53	42	2	11	8	12.1	12.3	Nil	Nil	Nil	Nil	NAD	NAD

SL.NO.	IP No.	SUG(mgs%)		UREA(mgs%)		CHOLESTEROL (mgs%)	
		BT	AT	BT	AT	BT	AT
1	2174	90	86	24	21	135	130
2	3194	89	68	30	25	161	119
3	3251	89	82	27	24	157	145
4	3246	99	95	15	14	158	137
5	3244	127	122	23	16	201	167
6	3314	81	77	41	38	186	175
7	34	142	90	24	22	214	221
8	56	103	97	20	17	170	155
9	83	114	98	38	29	280	260
10	101	80	75	36	29	210	185
11	136	108	91	30	26	160	135
12	168	117	76	16	21	149	128
13	190	101	98	25	21	184	173
14	253	126	97	19	17	180	195
15	309	120	99	23	20	188	185
16	587	102	98	22	18	261	218
17	836	101	97	29	21	189	165
18	837	99	95	21	19	176	165
19	865	131	125	38	32	139	128
20	932	99	92	29	21	195	186

INFERENCE:

Hematological studies:

Among the 40 patients, 5 of them found as anemic..

Cholesterol and urea were normal.

WBC Count:

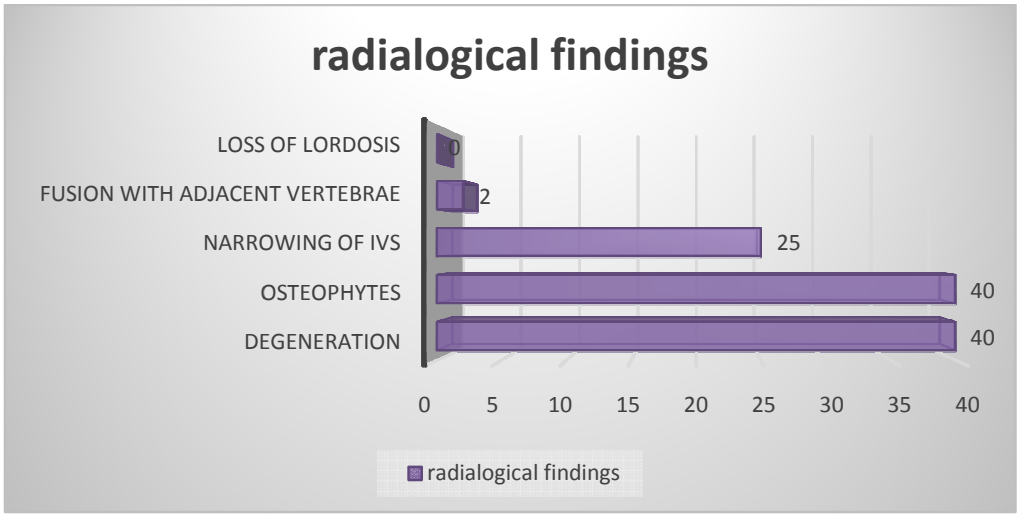
Total count was found in between 5000 to 10000. In few cases the eosinophil were little higher.

Erythrocyte sedimentation rate:

ESR was increased at th time of admission with the level of 5-55 per hour and it may decrease at the time of discharge.

17. Radiological findings:

Sl. No.	Radiological Findings	No of Cases	Percentage
1.	Degeneration	40	100
2.	Narrowing of IVS	25	62.5
3.	Osteophytic Changes	40	100
4.	Fusion of Osteophytes with adjacent vertebrae	2	5
5.	Loss of lordosis	-	-

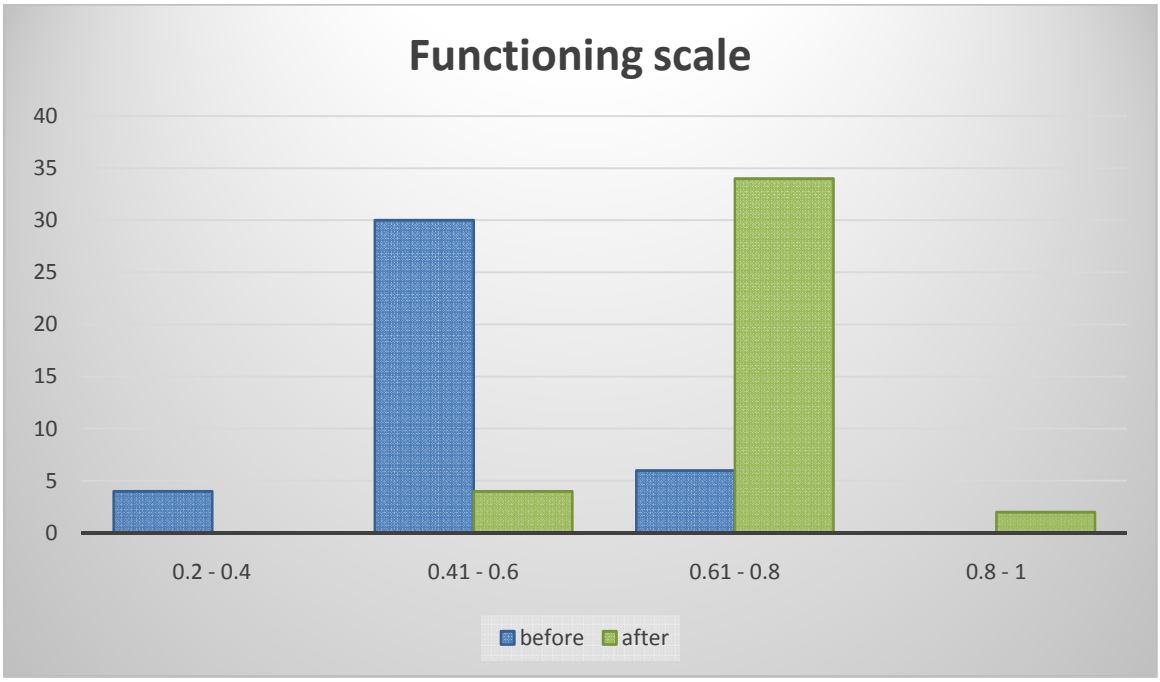


INFERENCE: All of the patients having degeneration and osteophytic changes. 25 patients (62.5%) having narrowing of IVS.

18. PAIN ASSESMENT SCALE:

A. Back pain functioning scale:

Maximum adjusted score	Before treatment	After treatment
0.2 - 0.4	**4**	**0**
0.41 – 0.6	**30**	**4**
0.61 – 0.8	**6**	**34**
0.81 – 1	**0**	**2**

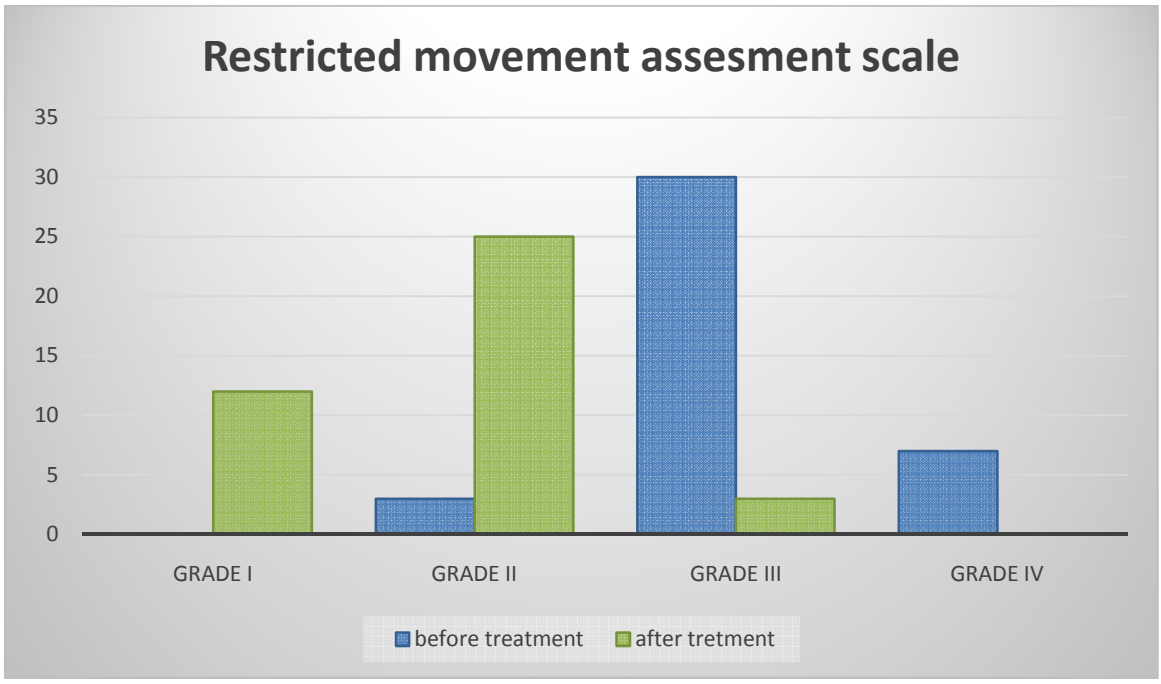


INFERENCE: The higher the score, the greater the patient's functional ability.

The maximum adjusted score before treatment was around 3 and after treatment upto 8.

B. Restriction movement assessment scale:

Gradation	No. of op cases	No.of i.p cases	Total No. of cases
Grade III –II	**10**	**11**	**21**
Grade III – I	**5**	**4**	**9**
Grade II – I	**3**	**0**	**3**
Grade IV – III	**1**	**2**	**3**
Grade IV – II	**1**	**3**	**4**



INFERENCE: Before treatment most of the patients having grade iii restriction, after treatment it downs to grade ii and grade i.

19. CURATIVE EFFECT OF VARMA ALONG WITH COMPLIMENTARY THRAPY(VARMAM):

Clinical Cure:

- No longer any clinical manifestations
- Patient could work and live normally
- No recurrence after 4 months

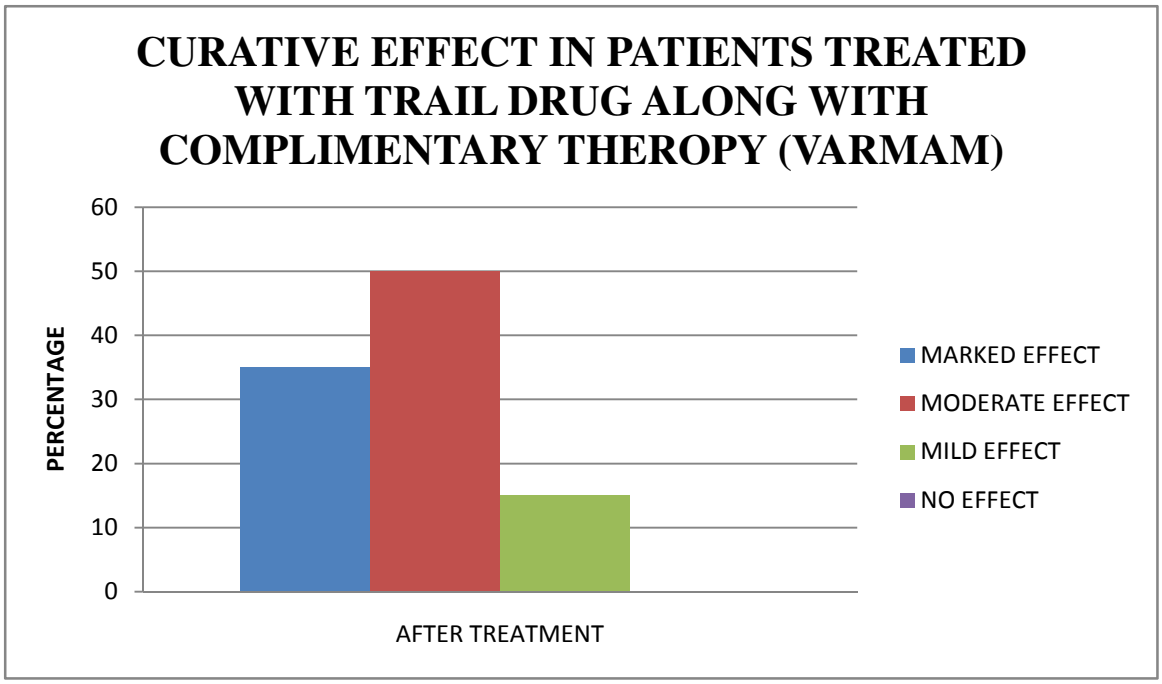
Marked Effect:

- Marked reduction of clinical manifestations
- Slight pain after exertion

Improvement:

- Some improvement in the regional symptoms
- With rela

S,NO	EFFECT OF DRUG ALONG WITH VARMA	NO.OF,PATIENT	PERCENTAGE (%)
1.	Marked effect	7	35
2.	Moderate effect	10	50
3.	Mild effect	3	15
4.	No effect	-	-



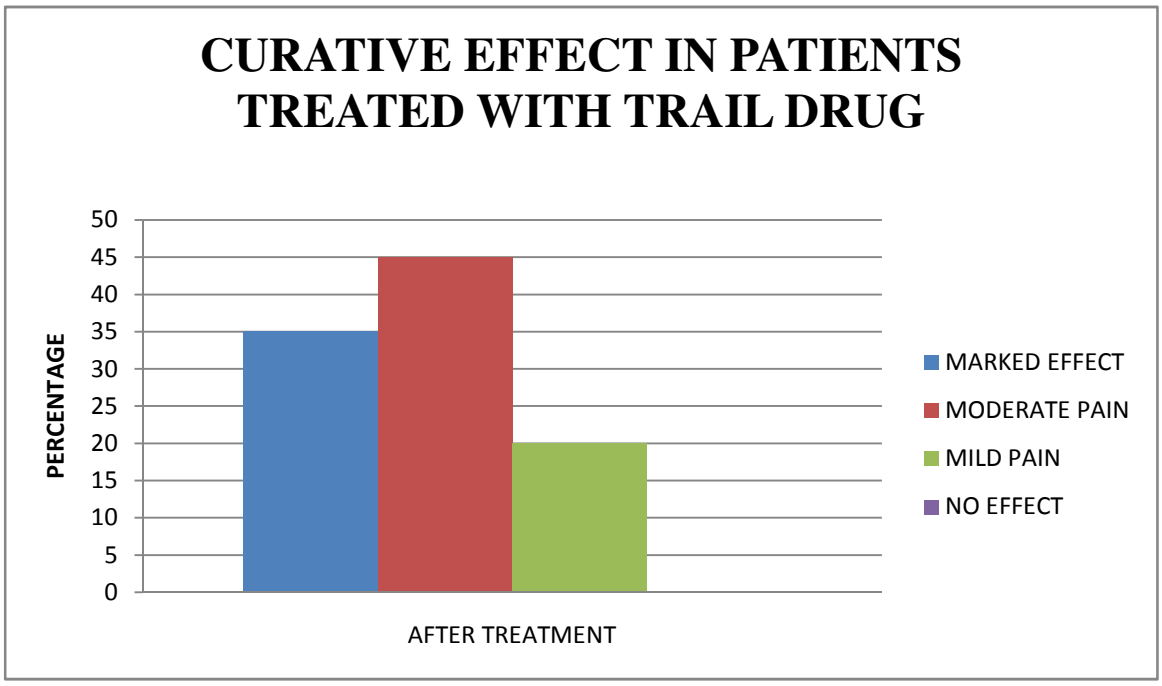
INFERENCE:

When the patients are treated along with complementary therapy,50% patients have moderate effect ,35% have the marked effect and 15% have mild effect

20.EFFECT OF TRIAL DRUG ALONE IN OPD:

Patients were treated only with trial drug medicine.

S.NO	EFFECT OF TRIAL DRUG ALONE	NO.OF.PATIENT	PERCENTAGE
1.	Marked effect	7	35
2.	Moderate effect	9	45
3.	Mild effect	4	20
4.	No effect	-	-



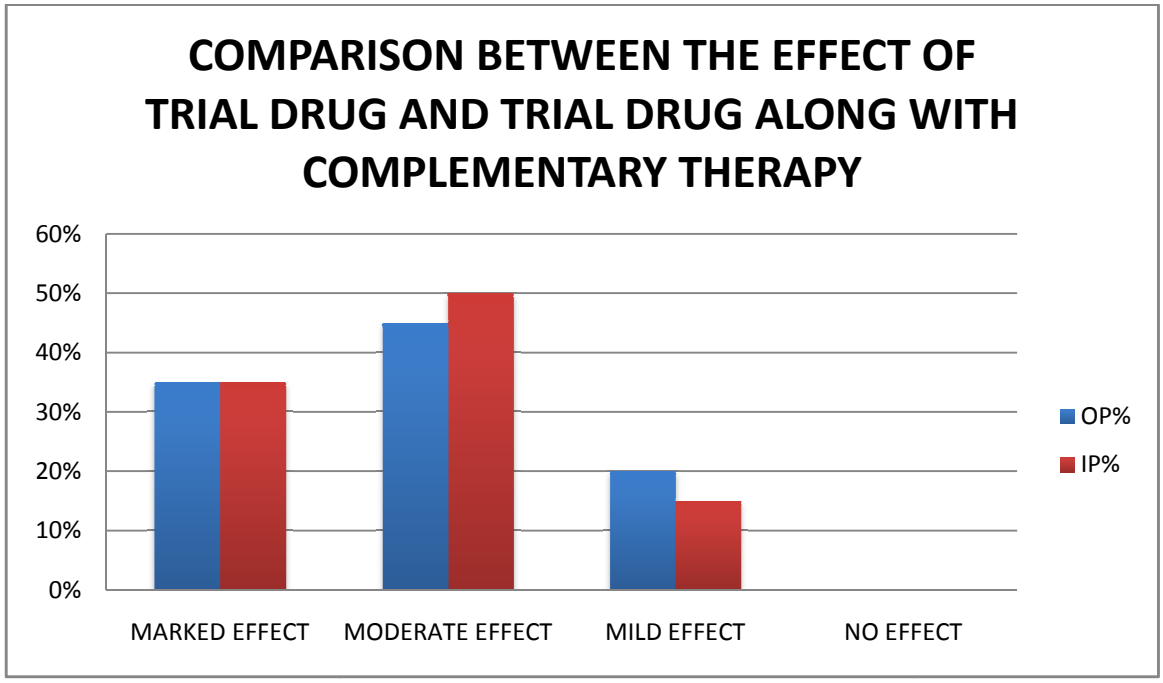
INFERENCE:

45% patients have moderate effect,35% have marked effect and 20% have mild effect when treated with trial medicine alone.

21.COMPARISON BETWEEN THE EFFECT OF TRIAL DRUG AND TRIAL DRUG DRUG ALONG WITH COMPLIMENTARY THERAPY:

Table21:

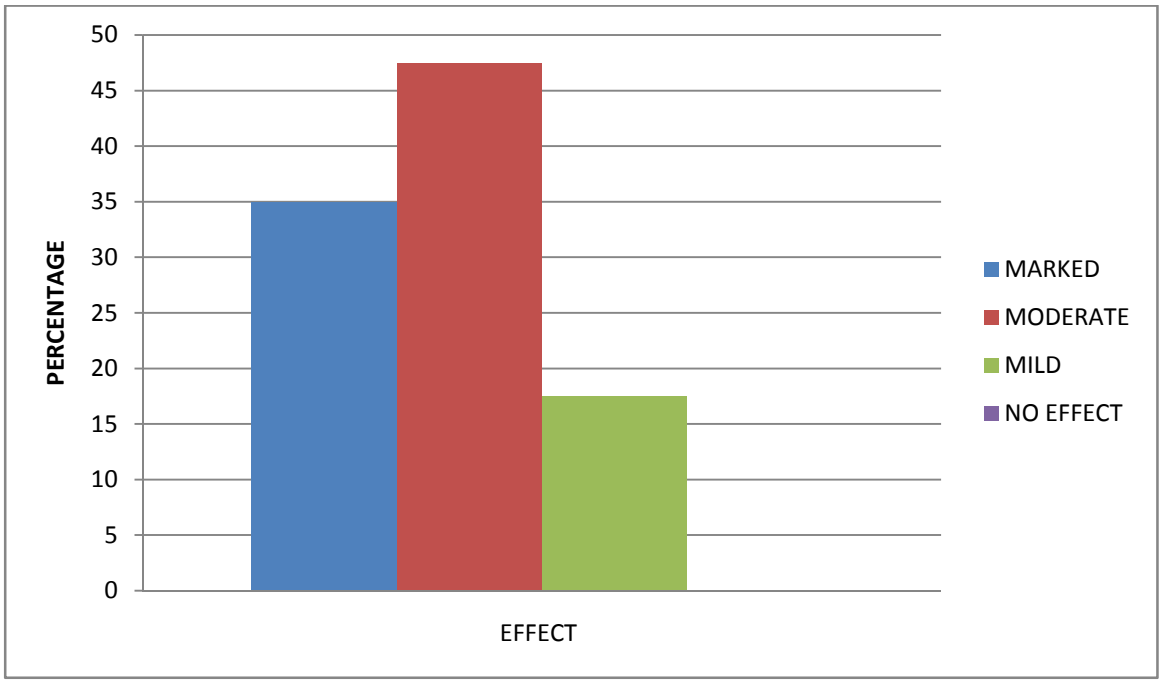
S.NO	EFFECT OF THERAPY	TRIAL DRUG ALONE		TRIAL DRUG ALONG WITH VARMAM	
		OP	%	IP	%
1.	Marked effect	7	35	7	35
2.	Moderate effect	9	45	10	50
3.	Mild effect	4	20	3	15
4.	No effect	-	-	-	-



22. Overall Curative effect (Based on number of cases treated):

S.NO	EFFECT OF THERAPY	NO.OF.CASES	PERCENTAGE
1.	Marked effect	14	35
2.	Moderate effect	19	47.6
3.	Mild effect	7	17.5
4.	No effect	-	-

EFFECT OF THERAPY



INFERENCE:

Thus from th end of the treatment,the data analysis says that the patient having moderate effect in 47.5%,marked effect in 35% and the mild effect in 17.5%

OUT PATIENT DEPARTMENT:

Sl.no	Op no.	Name	Age/sex	occupation	DOA	DOD	No. of days treated	Result
1	63877	Vijaya	54/F	Housewife	26/07/17	22/09/17	45	Marked
2	65820	Thangaraj	51/M	Cooli	02/08/17	10/10/17	47	Marked
3	70870	Peratchi	44/F	Housewife	18/08/17	15/12/17	46	Moderate
4	72235	Manikalakshmi	53/F	Housewife	23/08/17	31/11/17	47	Moderate
5	73846	Shanmugaraj	45/M	Autodriver	28/08/17	01/11/17	48	Marked
6	74990	Ramani	30/F	Beedirolling	31/08/17	01/11/17	48	Marked
7	75064	Rajsingh	34/M	Teashop	31/08/17	01/11/17	48	Moderate
8	81407	Krishnajeyanthi	44/F	Housewife	20/09/17	12/11/17	42	Mild
9	111084	Subramanian	42/M	Cooli	16/12/17	10/02/18	48	Mild
10	111088	Mytheenfathima	60/F	Hosewife	16/12/17	31/01/18	40	Moderate
11	112021	Fathima	25/F	Housewife	19/12/17	01/02/18	48	Moderate
12	111983	Maheshkumar	24/M	Supervisor	19/12/17	04/02/18	44	Marked
13	112279	Peratchi	60/F	Cooli	20/12/17	02/02/18	41	Mild
14	113753	Seyyad mahuth	52/M	Beedirolling	25/12/17	01/02/18	40	Moderate
15	114078	Karnamaharaja	29/M	Police	26/12/17	10/02/18	43	Marked
16	113357	Arul	54/M	Sparepart shop	27/12/17	12/02/18	41	Mild
17	348	Kanthasamy	58/M	Farmer	02/01/18	11/02/18	40	Moderate
18	297	K.S,Mani	52/M	Accountant	02/01/18	28/02/18	44	Marked
19	991	Prabhu	46/M	Marketing	02/01/18	18/03/18	40	Moderate
20	2398	Tamilselvi	50/F	Farmer	06/01/18	01/03/18	48	Moderate

INPATIENT DEPARTMENT:

Sl.no	Ip no.	Name	Age/sex	Occupation	DOA	DOD	No. of days treated	Result
1	2174	Subbaiah	58/M	Cooli	02/08/17	18/08/17	17	Moderate
2	3194	Kailasam	55/M	Cook	06/12/17	03/01/18	29	Marked
3	3251	Subbaiah	60/M	Groceryshop	12/12/17	03/01/18	23	Mild
4	3246	Thayammal	26/F	House wife	12/12/17	03/01/18	23	Moderate
5	3244	Rajkumar	39/M	Supervisor	12/12/17	12/01/18	37	Marked
6	3314	Petchammal	50/F	Cooli	19/12/17	12/01/18	25	Moderate
7	34	Malathi	36/F	Housewife	04/01/18	21/02/18	48	Marked
8	56	Gomu	60/F	Cooli	10/01/18	06/02/18	28	Mild
9	83	Lakshmanan	60/M	Retd.VAO	17/01/18	16/02/18	31	Marked
10	101	Subbulakshmi	60/F	Farmer	18/01/18	20/02/18	34	Moderate
11	136	Natarajan	55/M	Plumber	22/01/18	18/02/18	34	Moderate
12	168	Throwpathi	50/F	Housewife	24/01/18	06/03/18	42	Marked
13	190	Krishnammal	43/F	Housewife	25/01/18	01/03/18	36	Moderate
14	253	Vijayalakshmi	58/F	Housewife	01/02/18	23/02/18	23	Marked
15	309	Muthumari	49/F	Housewife	06/02/18	01/03/18	24	Moderate
16	587	Geethakumari	46/F	Cooli	05/03/18	03/04/18	30	Moderate
17	836	Ramalingam	60/M	Supplier	27/03/28	23/04/18	28	Mild
18	837	Nagammal	54/F	Housewife	27/03/28	20/04/18	25	Moderate
19	865	Pushpathai	60/F	Housewife	30/03/18	19/04/18	21	Marked
20	932	Samuvel	60/M	Cooli	06/04/18	30/04/18	25	Moderate

DISCUSSION

According to the clinical features mentioned in the yugi vaithiya chinthamani 800, forty patients were selected.with the help of siddha method of diagnosis and the modern investigation, diagnosis was endorsed and finally treated with the trial drugs and Special therapies. The observations are discussed here.

Sex distribution:

Females were found to be affected more in females.

Age Distribution

The significant statistical report shows that higher incidence was found to be with the age above 50 years, which is due to degenerative changes in the aging process is the important cause of lumbar spondylosis. Since this study is limited to patients below 60 yrs, it was not possible to study the incidence in people above this age limit.

Also most of the patients were known to be in Pitha kalam.

This information is bestowed by our Siddhars as the wordings.

"வேண்டா ஐம்பதாம் வயது தன்னில்
விரைந்து பிருதிவியில் அப்பு மேவும் பாரே"

The target sites affected in lumbar spondylosis are generally bones, muscles nerves, hairs, blood, urine, fat which are the components of appu and prithivi boothas (Appu + Prithivi = Kabam – responsible for destruction). Hence they starts degenerating above fifty years.

Thega nilai:

All patients were Thondha thegis.

Living Lands (Thinai)

The incidence of Thandagavatham is highest in people from Marutham.

Even though Siddha literatures mention Marutham as a disease free zone, most of the patients came from Marutham Nilam and few were from neithal thinai. This may be

due to the altered lifestyle, environment and food habits. Since this is a single centered study, located in marutham, it may also have influenced the study.

Socio Economic Status and occupation:

67.5% of people reported the signs and symptoms of Thandagavatham were middle class and this may be indirectly responsible for the higher incidence through their occupation. In contrast to much believed fact, considerable percentages of patients were housewives.

Seasonal Distribution:

Most of the patients came during munpani kalam and pinpani Kalam.

Precipitating Factors:

Eventhough the aging plays a major role in thandagavatham.the occupation may also precipates the major risk factor for the disease of low back ache.

Clinical Manifestations:

Low back pain and radiating pain in one oe both lower limb presents in all forty cases (100%).Restricted movement presents in 33 cases (82.5%).Numbness presents in 26 cases (65%) .These are the major clinical finding in thandagavatham.

Derangement in Vatham:

Viyanan,Samanan were affected in all 40 cases (100%).Dhevadhathan also affected in few cases.

Disturbances in Pitham:

Sathaga pitham was affected in all 40 cases (100%).

Derangement in Kabam:

Santhigam was affected in all 40 cases (100%).

Eight Parameters in our System

(Envagai Thervugal)

The analysis shows the efficacy of the envagai thervu and the prime significance of naadi.

Clinical Laboratory Investigations:

ESR was raised in early stage in many patients and after treatment it was reduced.

Incidence with reference to Radiological studies:

From X-ray lumbar spine (AP & Laterial view) and MRI, 100% cases shows the degenerative changes and osteophytic changes.

Narrowing of intervertebral space was seen in 62.5% of cases.

Treatment

The treatment was aimed to retain the deranged thoshas and providing relief from symptoms. Before treatment was initiated, the patients were advised to take Vellai ennai-15 ml with hot water at morning in th empty stomach for first day of treatment. The patient was asked to take rest from internal medicine and other activities on that day.

From 2nd day onwards, the patient was treated with the trail drugs **KUSTATHI CHOORNAM - 1gram with hot water and ERANDA THYLAM – 30 ml (EXTERNAL)**.During treatment, the patients were advised to follow pathiyam (avoid tamarind, tubers, etc) and advised to avoid pillows.But all aspect of pathiyam could not be followed due to practical difficulties.

SIRAPPU MARUTHUVAM TECHNIQUES [METHOD] APPLIED IN THANDAGA VATHAM PATIENTS

a) Varmam

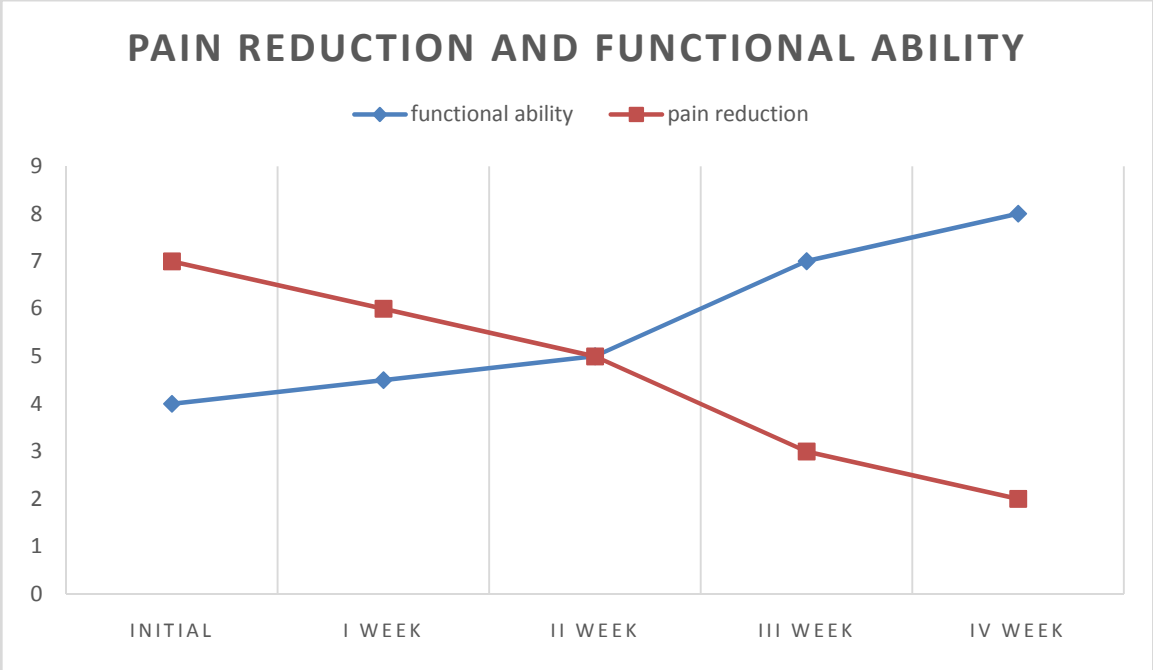
Among the forty cases, 20 cases were treated by varmam regularly.These 20 patients showed a positive quick response with their signs and symptoms when compared with other cases.

Pain Reduction and functional ability:

The back pain functioning scale and restricted movement assessment scale measurement recorded a significant reduction in pain, increase in range of motion and increase ability in daily activities.

The higher the score, the greater the patient's functional ability.

The maximum adjusted score before treatment was around 3 and after treatment it went upto 8.



Pharmacological studies done in Pharmacology of KMCH college of pharmacy, Coimbatore revealed that **Kustathi choornam** bears significant effect of Analgesic, Acute and chronic anti inflammatory action.**Eranda thylam** has analgesic and anti inflammatory effect.

Bio chemical analysis of drugs was done in the department of Bio-chemistry of Government Siddha Medical College and Hospital, Palayamkottai.Kustathi choornam contains **sulphate, ferrous iron,unsaturated compounds,reduced sugar and amino acid**.

SUMMARY

40 cases of thandagavatham were diagnosed clinically based on Yugi vaithiya chinthamani 800 and admitted in inpatient and outpatient ward of post graduate department of Sirappu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai and treated by the trial medicines.

- Laboratory diagnosis of thandagavatham was done by Siddha diagnostic principles and endorsed by modern methods of investigations.
- The various siddha principle of examinations were carried out and recorded in the proforma.
- The trial medicine chosen for both internal and external treatment were **kustathi choornam thrice a day with hot water internally and eranda hylam app;ied Externally.**
- The selection of patients and management of patients during admission and after treatment was carried out under the supervision of professor, reader, lecturer grade II of P.G. Sirappu maruthuvam department.
- Before starting the treatment, patient's history was taken and recorded for the selected forty cases.
- During the period of treatment all the patients were put under pathiyam (A specific dietary regimen).
- A periodical haematologocal investigation was made for all the cases.
- **Bio chemical analysis** of **Kustathi choornam** showed. Presense of sulphate, ferrous iron, unsaturated compound, reducing sugar and amino acid.
- The **pharmacological evaluation** of the **Kustathi choornam** had showed the significant analgesic and anti inflammatory actions. No acute toxicity effects were noted.
- The in patients are discharged after the prescribed time period as in protocol and advised to follow out patients ward.
- The observations made during the clinical study shows that the internal drug **Kustathi choornam** is clinically effective.
- Clinically the patient has marked reduction of low back pain with the radiating pain in the lower limb and restricted movements and decreases ESR was noted.
- Though there was appreciable clinical improvement.The action of external application **Eranda thylam** with Varmam is also quite remarkable.

CONCLUSION

Selected 40 patients were treated with internal trial drug **Kustathi choornam 1 gram with hot water** and **Eranda thylam 30 ml per day.**Varmam is given for 20 inpatients. Trial drug has the significant reduction of signs and symptoms.

- The trial medicine has significant analgesic and anti-inflammatory.
- Further follow up of all these patients showed the disappearance of signs and relief from symptoms.
- The trial medicines were free from side effects, adverse effects and toxic effects.

The effect of the drug were observed as:

- Marked effect – 35%
- Moderate effect – 47.5%
- Mild effect – 17.5%

This result of the clinical trial illustrates the good clinical effect of the trial drug and the complementary therapy.

ANNEXURE I

STANDARD OPERATING PROCEDURES THE PREPARATION OF KUSTATHI CHOORNAM AND ERANDA THYLAM:

SOURCE OF RAW DRUGS *:*

The required raw drugs for preparations of **KUSTATHI CHOORNAM** and **ERANDA THYLAM** are purchased from a authorized centers and raw drugs are identified and authenticated by the Medicinal Botanist of Govt. Siddha Medical College, Palayamkottai, then they are purified and the medicine is prepared in the P.G.Gunapadam Practical hall of Govt. Siddha Medical College, Palayamkottai.

INGREDIENTS :

KUSTATHI CHOORNAM (internal):

SL. NO	DRUGS	BOTANICAL NAME	PART USED	Amount
1	Kostam	Saussuria lappa	Root	1 palam (35gms)
2	Vetpalaivirai	Wrightia tinctoria	Seed	1palam (35 gms)
3	Chukku	Zingiber officinalae	Rhizome	1 palam (35gms)
4	Chitramoolam	Plumbago indica	Root	1palam (35 gms)
5	Athividayam	Aconitum heterophyllum	Root	1 palam (35gms)
6	Manjal	Curcuma longa	Rhizome	1palam (35 gms)

PURIFICATION OF RAW DRUGS

KOSTAM : Remove the adulterant and make it dry it on shade

VETPALAI VIRAI : Remove the adulterant and make it dry it on shade

MANJAL : Wash with water a allow it to dry

CHUKKU : Peel off the outer layer and allow to dry

CHITRAMOOLAM : The root will be baked in a steam of milk

ATHIVIDAYAM :Wash with water and allow it to dry

METHOD OF PREPARATION OF KUSTATHI CHOORNAM:

The above raw drugs are purified separatedly and allow it to dry in shade.The purified raw drugs are powdered separatedly and mix all together.Filter it with a white cloth.

ERANDA THYLAM (External)

S.No	INGREDIENT	BOTANICAL	PART USTP	MEASUREMENI
1.	Aamanakkuennai	Ricinus communis	Seed oil	1 Naali (1. 3litre)
2.	Milagu	Piper longum	Unriped fruit	½ palam (17.5gm)
3.	Manjal	Curcuma longa	Rhizome	½ palam (175 gm)
4.	Vellai Poondu	Allium sativum	Bulb	½ palam (17.5 gm)
5.	Kuppaimeni Saru	Acalypha indica	Whole plant	½ palam(720 ml)
6.	Kadugu	Brasica juncea	Seed	½ palam (17.5gm)

METHOD OF PREPARATION OF ERANDA THYLAM

Grind the above raw drugs to Kalkam mix the kalkam with kuppaimeni saaru.keep it in sunlight a day. At evening it will be mixed with oil and heat until ut reaches the required consistency. Filter it then kept in a airtight container.

DRUG STORAGE :

The trial drug **"KUSTATHI CHOORNAM" and "ERANDA THYLAM"** is stored in clean and dry air tight containers.

The siddha literature of the trial drugs are as follows:

DRUG REVIEW LITERATURE:

INTERNAL DRUG:

1.KOSTAM:

BOTANICAL NAME: Saussurea lappa

FAMILY: Asteraceae

VERNACULAR NAME:

Sanskrit: Pushkara

Bengali: Keu

Tamil: Koestam

Telugu: Kashmeeraamu

Malayalam: Channak Koova

Hindi: Kust

HABITAT: An elegant climbing Plant found Plentifully in Bengal and Kashmir.

PART USED: Root & Tuber.

ACTION: Root is bitter, Astrigent, Stimulant & digestive, Anthelmintic, depurative and aphrodisiac.

USES: Root is usefull in Catarrhal fevers, Coughs, Dyspepsia, Worms, Skin Diseases and Snake Bits. Tuber is cooked and made into a Cymys or presence which is very Wholesome.

கோட்டம் - Kottam

Costus speciosus

வேறு பெயர்: கோஷ்டம், குரா, ஒலி

ப.உ: வேர்

சுவை: கைப்பு, விறுவிறுப்பு **தன்மை :** வெப்பம் **பிரிவு : கார்ப்பு**

செய்கை:

பசித்தீத்தூண்டி	Stomachic
கோழையகற்றி	Expectorant
உரமாக்கி	Tonic
வெப்பமுண்டாக்கி	Stimulant
வியர்வைப்பெருக்கி	Diaphoretic

நாட்டிலுறு வெட்டை நடுக்கம் எனுநோய்கள்
கோட்டமெனச் சொன்னால் குலையுங்காண் - கூட்டிற்
சுரதோடந் தொண்டைநோய் தோலாத பித்தம்
பரதேசம் போமே பறந்து.

திட்டிகவுள் அகடுகளஞ் சென்னி நாவாய்
செறிபிணிவெப் பதைப்புதா வர்த்தம் ஊதை
முட்டியெழு முளைவிரணம் சுவாச காசம்
மூடிகத்தோ டரவுமர விடங்கள் மேகக்
கட்டிஅஜ கல்லிவிட பாகம் பூத
கணம்பால கிரகமொடு தாது நட்டஞ்
சொட்டிவரு பிரமிபித்தம் இவையொ ருங்கே
தொலையும்விர ணாரிக்குச் சுகப்போறோமே.

இத்தோடு தேன், வசம்பு, இவைகள் சேர்த்துக் கொடுக்க, வெறிநோய் நீங்கும்.

2.VETPALAIVIRAI:

BOTANICAL NAME: Holarrhena Anticlysenterica

FAMILY: Apocynaceae

VERNACULAR NAME:

Sanskrit: Kutaja

English: Kurchi

Tamil: Kashappu-Vetpalarishi

Telugu: Ka Ka Kodise

Hindi: Karchi

HABITAT:

This is small tree is common in Forests of India, Indigenous to the tropical Himalayas, Assam, Up &Down To Travancore. There are two Varieties- White & Black.

PART USED:

Bark, Seeds & Leaves.

CONSTITUENTS:

Bark a seed Contains.

A non oxygenated alkaloid-Wrightine or Conessine or Kurchisine and Holarrherine.

ACTION: (SEEDS)

Seeds which resemble oats, are very bitter

Astrigent, Febritage, anticlysenteric, anthelmintic, carminative and also antiperiodic in combination with other antiperiodics like cocculus cordifolius.

வெட்பாலை – Vetpalai

Wrightia – tinctoria (Roxb) R.Br

வேறு பெயர் :கிரிமல்லிகை, குடசம், வற்சம்

ப.உ: இலை, பட்டை, வித்து (அரிசி)

வித்து

சுவை : இனிப்பு **தன்மை :** தட்பம் **பிரிவு :** இனிப்பு

செய்கை:

வித்து

உரமாக்கி Tonic

இது, தீ வளிக் கூட்டின் பெருக்கையும், கடுவன், குடல் வாயு, வயிற்றுப் பொருமல், கழிச்சல் வகை முதலியவைகளைப் போக்கும்.

வெட்பாலை தன்னரிசி வீறுபித்த வாதமொடு
கொட்பார் கரப்பான் குடல்வாத - உப்பிசத்தைக்
காணாம லேநாளுங் கண்டிக்குங் காசினியிற்
பூணார் முலையா புகல

3.CHUKKU:

BOTANICAL NAME: Zingiber officinale

FAMILY: Zingiberaceae

VERNACULAR NAMES:

Eng: Dried ginger

Tel: Sonti

Kan: Ona shunti or sunti

Sans: Nagaram

Hindi : Sonth

HABITAT: Widel distributed in tropical asia,cultivated in many parts of india on large scale.A herbaceous,rhizomatous perennial reaching upto 90cm in height under cultivation.

PART USED:Rhizome

CONSTITUTIONS:

Dried ginger contains 1-2% volatile oil, camphene, zingiberene, zingiberoleucalyptol, yellow oil gingerol, phenols, resins, zingerone.

ACTION: Analgesic and anti-pyretic activity.

சுக்கு-Chukku

Zingiber Officinale, Rosc

வேறு பெயர்:அருக்கன், அதகம், ஆர்த்ரகம், உபகுல்லம், உலர்ந்த இஞ்சி, கடுபத்திரம், சுக்கு, சுண்டி சொண்டி, சௌபன்னம், சௌவர்ணம், நவசுறு, நாகரம், மநௌஷதம், விச்வ பேஷஜம், விடமுடிய அமிர்தம், வேர்க்கொம்பு.

ப.உ: கிழங்கு (உலர்ந்தது)

சுவை: கார்ப்பு **தன்மை:** வெப்பம் **பிரிவு :** கார்ப்பு

செய்கை:

வெப்பமுண்டாக்கி	Stimulant
பசித்தீத்தூண்டி	Stomachic
அகட்டுவாய்வகற்றி	Carminative

குணம்:சுக்கினால், செரியாமை, மார்பெரிச்சல், புளியேப்பம், வெப்பம், கீழ்வாய் நோய், இரைப்பு, இருமல், கழிச்சல், நீரேற்றம், குன்மம், வயிற்றுப்பிசம், காதுக் குத்தல்,முகநோய், தலை நோய், குலைவலி, பாண்டு, வயிற்றுக் குத்தல், ஐயசுரம் போம்.

சூலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை
மூலம் இரைப்பிருமல் மூக்குநீர்-வாலகப
தோடமதி சாரந் தொடர்வாத குன்மநீர்த்
தோடம்ஆ மம்போக்குஞ் சுக்கு.

வாதப் பிணிவயி றூதற் செவிவாய்
வலிதலை வலிகைல வலியிரு விழிநீர்
சீதத் தொடுவரி பேதிப் பலரோ
சிகமலி முகமக முகமிடி கபமார்
சீதச் சுரம்பிரி போதச் சுரநோய்
தெறிபடுமெனமொழி குவர்புவி தனிலே
ஈதுக் குதவுமி தீதுக் குதவா
தெனும்விதி யிலைநவ சுறுகுண முனவே.

4.CHITRAMOOLAM:

BOTANICAL NAME: Plumbago zeylanica

FAMILY: Plumbaginaceae

VERNACULAR NAMES:

Sanskrit: Chitraka

English: Ceylon Leadwork

Telugu: Agnimatha

Hindi: Chitra

Bengali: Chita

Malayam: Vellakotuveri

HABITAT: This garden plant is growing will in Bengal, UP Southern India and Ceylon. This is an allied species and is considered to be a cultivated variety of P Rosea.

PART USED: Root

CONSITUTENT: Fluckiger (1889) isolated plumbagin from the root in a porer form, Roy &Dutt(1928) have found that "Plumbagin" is present in all the varieties of Plumbago with in India.

"Plumbagin" has the property of setting up irritation of the Skin.

ACTION: Root is said to increase the digestive power and promote the apptite.

Kelenka(1931) finds that plumbagin stimulates the central nervous system is small dose while with layer closes Paralysiis sets in leading ultimately to Death. The blood pressure Should a Slight fall.

கொடிவேலி– Kodiveli

Plumbago indica

வேறு பெயர்: அணிஞ்சில், அதிகநாரி, அதிபதுங்கி, அழல், உதாசனன், எரி, எழுநா, ஒலி, கருநாகம், கனலி, காரிமை, கொடுவேலி, கானிலிந்திரன், கானிலம், கொடிச்சி, சித்திரமூலி, சித்திரமூலம், சித்திரம், ஞெகிழி, தழல், திக்கு, திசைநா, வஞ்சதாரம், வன்னி, அக்னி, அதிசனசி உதகவன், சதாவேதா, சித்திரகம், தபனன், திகனா, வசகம், வனமா, வன்னிபரியம், சித்ரகம், கொடிவன்னி, வலிவன்னி, திவிபிநாமம்.

பொதுக் குணம்: இதனால், கட்டி, புண், கழலை, வளிநோய், அரையாப்புக்கட், குத்தல், சோபை, மூலரோகம், உதிரக்கட்டு, நீரேற்றம், பெருவயிறு இவைபோம்.

கட்டிவிர ணங்கிரந்தி கால்கள் அரையாப்புக்
கட்டிச்சூ லைவீக்கங் காழ்மூலம்-முட்டிரத்தக்
கட்டுநீ ரேற்றங் கனத்த பெருவயிறும்
அட்டுங் கொடிவேலி யாம்.

வெண்கொடிவேலி - Venkodiveli

Plumbago Zeylanica. Linn

வேறு பெயர் :வெண்சித்திரமூலம், வெண்கொடிமூலம்

சுவை :கார்ப்பு, விறுவிறுப்பு **தன்மை** : வெப்பம் **பிரிவு** : கார்ப்பு

செய்கை:

முறைவெப்பகற்றி	Anti-periodic
வியர்வையுண்டாக்கி	Diaphoretic

வாயுவினாலுண்டாகும், உடம்புக்குத்தல் போம்.
கருணைமூலம், அரையாப்பு, கண்டமாலை.

5.ATHIVIDAYAM:

BOTANICAL NAME: Aconitum hetrophyllum:

FAMILY: Ranusculaceae

VERNACULAR NAMES:

Sanskrit: Ativisha

English: Indian atees

Telugu: Ativasu

Hindi: Atis

Bengali: Ataicha

HABITAT: Sub-Alpine and Allpine Zones, the Himalayas from Indus to Kumaori.

Part Used: Dried tuberous roots

CONSTITUENT: Atisine, Aconitinic acid, Tannic acid, Pectous Substance, Abudant starch, a mixture of oleic, Palmitic Stearic glycerides, vegetables mucilage, cane sugar and ash 2-percent

ACTION: Roots are bitter tonic, astringent, Stomachic, antiperiodic and aphrodisiac.

அதிவிடயம் - Ati-Vidayam

Aconitum heterophyllum Wall-ex Royle

வேறு பெயர்:-அத்திரணம், பங்குரை, மாதிரி

ப-உ : வேர்

சுவை : கைப்பு **தன்மை :** வெப்பம் **பிரிவு :** கார்ப்பு

செய்கை:

பசித்தீத்தூண்டி	Stomachic
துவர்ப்பி	Astringent
வெப்பகற்றி	Febrifuge
ஆண்மை பெருக்கி	Aphrodisiac
உரமாக்கி	Tonic
முறைவெப்பகற்றி	Antiperiodic

6.MANJAL:

BOTANICAL NAME: Coscinium fenestraterm

FAMILY : Menispermaceae

VERNACULAR NAME:

Sanskrit: Daru-haridrakam

English:Tree-Turmeric

Bengali:Haldi-gack

Tamil:Mara-Majal

Telugu:Manu-Pasupes

HABITAT: In all parts of India, especially Western India.

PART USED:Stem

CONSTITUENTS: Stem Contains Berberine and Saponin in small quantities.

ACTION: Root is bitter, Stomactic, tonic and is a very good substitute for Columba.

USES: A part of its is applied to the head as a cooling applications and also to bruises, Contusions etc. it is very useful in the form of infusion or tincture in continued and intermittent fevers, in general debility especially after fevers and in certain forms of Dyspepsia, in ulcers and in snake bites.

மஞ்சள்- Manjal

Curcuma longa. Linn

வேறு பெயர்: அரிசனம், கான்சனி, நிசி, பீதம்

கறிமஞ்சள் - கிழங்கின் பக்கங்களிற் கிளைக்கும் விரற்போலுள்ளவைகளை வேறுபடுத்தி, சாணப்பாலில் வேகவைத்துப் பக்குவப்படுத்துவது.

ப.உ :கிழங்கு

சுவை: கார்ப்பு, கைப்பு **தன்மை** : வெப்பம் **பிரிவு** : கார்ப்பு

செய்கை:

மணமூட்டி	
அகட்டுவாய்வகற்றி	Carminative
வெப்பமுண்டாக்கி	Stimulant
ஈரல்தேற்றி	Hepatic Tonic

குணம்:

உடலிற் பூசிக்குளிக்க உடலுக்குப் பொன்னிறம் தரும். புலால் நாற்றத்தை நீங்கும். ஆண்கள் மனத்தைக் கவரச்செய்யும் பசியையுமுண்டாக்கும். இதனால் வாந்தி, வளி,

தீ,ஐயக்குற்றம், தலைவரி, நீரேற்றம், வெள்ளை, மூக்குநீர்பாய்தல், ஐவகைவலி, வீக்கம், வண்டுகடி, பெரும்புண் இவைபோம்.

பொன்னிறமாம் மேனி புலானாற்ற மும்போகும்
மன்னு புருட வசியமாம் - பின்னியெழும்
வாந்திபித்த தோடமையம் வாதம்போந் தீபமாங்
கூந்தமஞ்ச ளின்கிழங்குக்கு.

இதன் மணத்திற்காகவும், நிறத்திற்காகவும், நாம் உண்ணும் உணவில் இதனைச் சோர்ப்பதுணடு.

INTERNAL DRUGS

KOSTAM

VETPALAIVIRAI

CHUKKU

KODIVELI

MANJAL

ATHIVIDAYAM

EXTERNAL DRUG:

1.**AAMANAKUENNAI**:

BOTANICAL NAME: Ricinus communis

FAMILY: Euphorbiaceae

VERNACULAR NAMES:

Sanskrit: Eranda

Hindi: Endi

Bengali: Verenda

Telugu: Eramudapu

Maalayalam: Chittamanakku

HABITAT: This plant is Common and quite wild in the Jungles of India and is by far the largest producer. It is Cultivated throughout India Chiefly in the Madras, Bengal and Bombay Presidencies

Part Used: Oilleaces, wets & Seeds

CONSTITUENT: The oil Chiefly consist of ricinoleate of glycerol 1 or tri-ricinolein with a small quantity of palmittin and Stearin

வேறுபெயர்:- ஏரண்டம், சித்திரம், தலரூபம்

செய்கை:

மலமிளக்கி Laxative

வறட்சியகற்றி Emollient

உடலைப் பொன்னிறமாக்கும்

ஆமணக்கு நெய்யால் நலமுண்டாம் யாவர்க்கும்
பூமணக்கு மேனி புரிகுழலே - வாய்மணக்கக்
கொள்ளில் வயிறுவிடுங் கோரமுள்ள வாயுவறும்
உள்ளில்வரு குன்மம்போ மோது.

2.MILAGU:

BOTANICAL NAME: Piper nigrum

FAMILY: Piperaceae

VERNACULAR NAME:

Sanskrit: Marichaam

English: Black pepper

Telugu: Miriyalu

Malayalam: Keeru- Mulaka

Bengali: Kalimirich

HABITAT: This perennial climbing shrub is indigenous to Malabar and Travancore Coats, ie,. Western Coat of India

Part Used: Dried unique fruits

CONSITUTENT: A voltaic alkaloid peprine or pipurine 5 to q pc, Piperdine or puperidin 5 pc a balsamic voltaic Esstential oil1to 2 pc, 7pc Mesocay Contant Charicin, babamic Voltaic oil, Starch, Lignin, Gum, Fat 1 pc, Proteins 7 pc, Ash Containing organic Matter 5 pc

ACTION: Black pepper is acids, Pungent, Hot Carminative also used ad antiperiodic.

EXTERNALLY: It is rubefacient & stimulant to the skin &resolvent , piperine is a mild antipyretic & antiperiodic

மிளகு– Milagu

Piper nigrum.Linn

வேறு பெயர்: கலினை, கறி,காயம், கோளகம், திரங்கல், மிரியல், சருமபந்தம், வள்ளிசம், மாசம்,குறுமிளகு, மலையாளி.

ப.உ: விதை, கொடி

சுவை :கைப்பு, கார்ப்பு **தன்மை:** வெப்பம் **பிரிவு :** கார்ப்பு

செய்கை:

காறலுண்டாக்கி	Acrid
அகட்டுவாய்வகற்றி	Carminative
முறைவெப்பகற்றி	Antiperiodic
தடிப்புண்டாக்கி	Rubefacient
வெப்பமுண்டாக்கி	stimulant
விக்கங்கரைச்சி	Resolvent
வாதமடக்கி	Antivatha
நச்சரி	Antidote

சீதசுரம் பாண்டு சிலேத்மங் கிராணிகுன்மம்
வாதம் அரசிபித்தம் மாமூலம் - ஓதுசன்னி
யாசமபஸ் மாரம் அடன்மேகம் காசமிவை
நாசங் கறிமிளகினால்

தீயாகி யெங்கும் திரியுமதை யாவத்து
மோயாம லெப்படியு முண்டாக்காற் - பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரம் மண்ணவர்க்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்.

மிளகு, வளி, தீ, கபக்குற்றங்கள் இவை அனைத்தையும் நீக்கும். அன்றியும், திமிர்வாதம், கழலை, வளி, சளி இவைகளையும் அகற்றும்.

3.MANJAL:

BOTANICAL NAME: Coscinium fenestraterm

FAMILY **:** Menispermaceae

VERNACULAR NAME:

Sanskrit: Daru-haridrakam

English:Tree-Turmeric

Bengali:Haldi-gack

Tamil:Mara-Majal

Telugu:Manu-Pasupes

HABITAT: In all parts of India, especially Western India.

PART USED: Stem

CONSTITUENTS: Stem Contains Berberine and Saponin in small quantities.

ACTION: Root is bitter, Stomactic, tonic and is a very good substitute for Columba.

USES: A part of its is applied to the head as a cooling applications and also to bruises, Contusions etc. it is very useful in the form of infusion or tincture in continued and intermittent fevers, in general debility especially after fevers and in certain forms of Dyspepsia, in ulcers and in snake bites.

மஞ்சள்- Manjal

Curcuma longa. Linn

வேறு பெயர்: அரிசனம், கான்சனி, நிசி, பீதம்

கறிமஞ்சள் - கிழங்கின் பக்கங்களிற் கிளைக்கும் விரற்போலுள்ளவைகளை வேறுபடுத்தி, சாணப்பாலில் வேகவைத்துப் பக்குவப்படுத்துவது.

ப.உ :கிழங்கு

சுவை: கார்ப்பு, கைப்பு **தன்மை** : வெப்பம் **பிரிவு** : கார்ப்பு

செய்கை:

மணமூட்டி	
அகட்டுவாய்வகற்றி	Carminative
வெப்பமுண்டாக்கி	Stimulant
ஈரல்தேற்றி	Hepatic Tonic

குணம்:

உடலிற் பூசிக்குளிக்க உடலுக்குப் பொன்னிறம் தரும். புலால் நாற்றத்தை நீங்கும். ஆண்கள் மனத்தைக் கவரச்செய்யும் பசியையுமுண்டாக்கும். இதனால் வாந்தி, வளி, தீ,ஐயக்குற்றம், தலைவரி, நீரேற்றம், வெள்ளை, மூக்குநீர்பாய்தல், ஐவகைவலி, வீக்கம், வண்டுகடி, பெரும்புண் இவைபோம்.

பொன்னிறமாம் மேனி புலானாற்ற மும்போகும்
மன்னு புருட வசியமாம் - பின்னியெழும்
வாந்திபித்த தோடமையம் வாதம்போந் தீபமாங்
கூர்ந்தமஞ்ச ளின்கிழங்குக்கு.

இதன் மணத்திற்காகவும், நிறத்திற்காகவும், நாம் உண்ணும் உணவில் இதனைச் சோர்ப்பதுண்டு.

4.VELLAI POONDU:

BOTANICAL NAME: Allium sativum:

FAMILY: Liliaceae

VERNACULAR NAME:

Sanskrit: Lasuna

English: Garlic

Telugu: Tellagaaedda

Malayalam: Vellulli

Bengali: Rasun

HABITAT: Cultivated all over India

Part Used: Bulb & Oil

CONSITUTENT: An Acid volatile oil starch, Mucilage, Albumen, Sugar etc

ACTION: Hot, Stimulant, Carminative, emmenagogue, antirheumatic, anthelmintic and alternative

வெள்ளுள்ளி – Vellulli

Allium sativum.Linn

வேறு பெயர்: இலகனம்,காயம், உள்ளி, பூண்டு, வெள்ளைப்பூண்டு, வெள்வங்காயம்.

ப.உ: கிழங்கு

சுவை: கார்ப்பு **தன்மை :** வெப்பம் **பிரிவு :** கார்ப்பு

செய்கை:

அகட்டுவாய்வகற்றி	Carminative
பசித்தீத்தூண்டி	Stomachic
உரமாக்கி	Tonic
உடற்றேற்றி	Alterative
வெப்பமுண்டாக்கி	Stimulant
கோழையகற்றி	Expectorant
சிறுநீர்ப்பெருக்கி	Diuretic
புழுக்கொல்லி	Anthelmintic

குணம்:

இதைச் சிறிய கட்டிகள், செவிடு. நாட்பட்ட இருமல், இரைப்பு, வயிற்றுப்புழு இவைகட்கும், முப்பிணி, வளிநோய்கள், ஐயத்தலைவலி, வாய்நோய், நீரேற்றம், சீதக்கழிச்சல், மூலம் இவைகட்கும் கொடுக்கலாம்.

சன்னியொடு வாதந் தலைநோவு தாள்வலி
மன்னிவரு நீர்க்கோவை வன்சீதம் - அன்னமே!
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு.

5.KUPPAIMENI SAARU:

BOTANICAL NAME: Acalypha indica:

FAMILY: Euphorbiaceae

VERNACULAR NAMES:

Sanskrit: Arittermanjarie

English: Indian Acalypha

Telugu: Keippeichhettu

Hindi: Keepu

Bengali: Muktajjhuri

HABITAT: Common annual shrub in Indian gardens and waste places throughout the plains of India.

PART USED: Leaves, Root, Stalk & Flowers

CONSITUENTS: Alkaloids “Acalypus & Acalyphine”

ACTION: Cathartic anthelmintic, expectorant, enatic anaelyne & hyppotic.

குப்பைமேனி – Kuppai-meni

Acalypha indica. Linn

வேறு பெயர்: அரிமஞ்சரி, பூனைவணங்கி, மேனி.

ப.உ: இலை, வேர்,சமூலம்

சுவை: கைப்பு, கார்ப்பு **தன்மை** : வெப்பம் **பிரிவு** : கார்ப்பு

செய்கை:

துயரடக்கி	Anodyne
புழுக்கொல்லி	Anthelmintic
பெருமலம்போக்கி	Cathartic
சிறுநூர்ப்பெருக்கி	Diuretic
வாந்தியுண்டாக்கி	Emetic
கோழையகற்றி	Expectorant
சூதகமுண்டாக்கி	Emmenagogue

குணம்:

இதன் இலையால், பல்லடி நோய், தீச்சுட்டப்புண், பயிர் வகையின் நஞ்சு, வயிற்றுவலி, வளிநோய், மூலம், நமைச்சல், குத்தல், இரைப்பு, மூக்குநீர் பாய்தல், கோழை ஆகியவை நீங்கும்.

தந்தமூ லப்பிணிதீத் தந்திடுபுண் சர்வவிடம்
உந்துகுன்மம் வாதம் உதிரமூ-லந்தினவு
சூலஞ்சு வாசம் தொடர்பீ சங்கபம்போம்
ஞாலங்கொள் மேனியத னால்.

6. KADUGU:

BOTANICAL NAME: Brassica juncea.

FAMILY: Cruciferae

VERNACULAR NAMES:

Sanskrit: Rajika

English: Common Indian or brow mustard

Bengali: Rai sarisha

Telugu: Avalu

Malayalam: Kaduka

HABITAT: Cultivated in many parts in India

Part Used: Seeds And Oil

CONSTITUENT: Seeds contains about do to 25 per cent of oil. An essential oil is also produced by the action of water

ACTION: Whole plant possesses bitter, aperients and tonic properties , Oil in Stimulant and counter irritant. A hot mustard batts is an emminaagogue

EXTERNAL DRUGS

AMANAKU OIL

MANJAL

VELLAIPOONDU

KUPPAIMENI SARU

KADUGU

MILAGU

வேறுபெயர் :ஐயவி

செய்கை:

வாந்தியுண்டாக்கி	Emetic
வெப்பமுண்டாக்கி	Stimulant
துடிப்புண்டாக்கி	Rubefacient
கொப்புளமெழுப்பி	Vesicant
செரிப்புண்டாக்கி	Digestive
சிறுநீர்ப்பெருக்கி	Diuretic

குணம்:

இது தலையிடிப்பைத் தரக்கூடிய இருமல், மூக்குநீர் வடிதல் கோழை, வெறி, காணாவிடக் கடி, குடைச்சல், முடம், மந்தம்,குழம்பிய உமிழ்நீர், கழிச்சல், வயிற்றுவலி, முப்பிணி, இவைகளை விலக்கும். மேலும், சீதக்கடுப்பு, கீல் வாயு, செரியாமை, தலை சுற்றல், விக்கல் இவைகளையும் போக்கும்.

இடிகாச நாசிக்சூ ரீளைகபம் பித்தங்
கடிவாத சீதங் கடுப்போ - டுடலிற்
படுகோட்டு நோயென்னும் பங்கிவைக ளைப்புண்
கடுகோட்டு மேன்மருந்து காண்.

INTERNAL DRUG – KUSTATHI CHOORNAM

EXTERNAL DRUG – ERANDA THYLAM

ANNEXURE – II

BIO – CHEMICAL ANALYSIS

BIO – CHEMICAL ANALYSIS OF KUSTATHI CHOORNAM

PREPARATION OF THE EXTRACT

5gms of drug was weighed accurately and placed in a 250ml clean beaker. Then 50ml distilled water was added and dissolved well. Then it was boiled well for about 10 minutes. It was cooled and filtered in a 100ml volumetric flask and then it was made up to 100ml with distilled water. This fluid was taken for analysis.

Qualitative Analysis

S.No	Experiment	Observation	Inference
1.	**Test for calcium:** 2ml of the above prepared extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxalate solution.	No white precipitate formed.	Absence of calcium.
2.	**Test for sulphate:** 2ml of the extract is added to 5% barium chloride solution.	A white Precipitate is formed.	Indicates the presence of sulphate.
3.	**Test for chloride:** The extract is treated with silver nitrate solution.	No precipitate formed.	Absence of chloride.

4.	**Test for carbonate:** The substance is treated with concentrated Hcl	No brisk effervescence formed.	Absence of carbonate.
5.	**Test for Starch:** The extract is added with weak iodine solution.	No Blue colour formed	Absence of starch.
6.	**Test for Iron Ferric:** The extract is treated with concentrated glacial acetic acid and potassium ferro cyanide.	No blue colour formed.	Absence of ferric iron.
7.	**Test of Iron Ferrous:** The extract is treated with concentrated Nitric acid and ammonium thio cyanate solution.	Blood red colour Is formed.	Indicates the presence of ferrous iron.
8.	**Test for phosphate:** The extract is treated with ammonium molybdate and concentrated nitric acid.	No Yellow precipitate formed.	Absence of phosphate.
9.	**Test for albumin:** The extract is treated with Esbach's reagent.	No yellow precipitate formed.	Absence of albumin.

10.	**Test for Tannic acid:** The extract is treated with ferric chloride reagent.	No Blue black precipitate formed.	Absence of Tannic acid.
11.	**Test for unsaturation:** Potassium permanganate solution is added to the extract.	It gets decolorized.	Indicates the presence of unsaturated compound.
12.	**Test for the reducing sugar:** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8-10 drops of the extract and again boil it for 2 minutes.	Colour change occurs.	Indicates the presence of reducing sugar.
13.	**Test for amino acid:** One or two drops of the extract is placed on a filter paper and dried it well. After drying, 1% ninhydrin is sprayed over the same and dried it well.	Violet colour formed.	Indicates the presence of amino acid.
14.	**Test for zinc:** The extract is treated with Potassium ferrocyanide.	No white precipitate is formed	Absence of zinc.

Inference:

The given sample of "**Kustathi choornam**" contains sulphate, ferrous iron, amino acids, unsaturated compoundand reduced sugars.

PHYSIOCHEMICAL ANALYSIS OF –KUSTATHY CHOORANAM

1. **Loss On Drying:**

   An accurately weighed 2g of ***Kustathy Chooranam*** formulation was taken in a tarred glass bottle. The crude drug was heated at 105^0C for 6 hours in an oven till a constant weight. Percentage moisture content of the sample was calculated with reference to the shade dried material.

2. **Determination of total ash:**

   Weighed accurately 2g of ***Kustathy Chooranam*** formulation was added in crucible at a temperature 600^0C in a muffle furnace till carbon free ash was obtained. It was calculated with reference to the air dried drug.

3. **Determination of acid insoluble ash:**

   Ash above obtained, was boiled for 5min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was burnt to a constant weight in a muffler furnace. The percentage of acid insoluble as was calculated with reference to the air dried drug.

4. **Determination of water soluble ash:**

   Total ash 1g was boiled for 5min with 25ml water and insoluble matter collected on an ash less filter paper was washed with hot water and ignited for 15 min at a temperature not exceeding 450^0C in a muffle furnace. The amount of soluble ash is determined by drying the filtrate.

5. **Determination of water soluble Extractive:**

   5gm of air dried drug, coarsely powered ***Kustathy Chooranam*** was macerated with 100ml of distilled water in a closed flask for twenty-four hours shaking frequently. Solution was filtered and 25 ml of filtrated was evaporated in a tarred flat bottom shallow dish, further dried at 100^0 C and weighted. The percentage of water soluble extractive was calculated with reference to the air dried drugs.

6. **Determination of alcohol soluble extractive:**

   2.5gm. of air dried drugs, coarsely powdered ***Kustathy Chooranam*** was macerated with 50 ml. alcohol in closed flask for 24 hrs. With frequent shaking it was filtered rapidly taking precaution against loss of alcohol. 10ml of filtrate was then evaporated in a tarred flat bottom shallow dish, dried at 100^0C and weighted.

The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

S.no	Parameters	Percentage
1	Loss on drying	5.88%
2	Total ash value	4.28%
3	Acid insoluble ash	Less than 1%
4	Water soluble ash	Less than 1%
5	Water soluble extraction	70.01%
6	Alcohol soluble extraction	12.74%

The above stated physiochemical properties for the given sample certified to be present.

EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON CARRAGEENAN-INDUCED LOCALISED INFLAMMATORY PAIN IN RATS

SUMMARY

The study plan was developed based on the guidelines of Vogel[1] and also it has reference to Chao Ma and Jun-Ming Zhang[2] and Walker et al. [3,] Winter CA, Risley EA, Nuss GW. Carrageenin induced edema in hind paw of the rat as an assay for anti-inflammatory drugs. Proc Soc Exp Biol Med. 1962;111:544–7.

Objective

To study the anti-inflammatory effect of **KUSTATHI CHOORNAM** were prepared **with HOT WATER** in the rat model of Carrageenan-induced localized inflammation.

Methods:

Test System

Species	:	Rat
Strain	:	Albino Wister
Age	:	6-8 weeks at the time of dosing
Total no. of Rats	:	24
Sex	:	Male
Weight	:	150 gm

The animals were housed in polypropylene cages with stainless steel top grills having facilities for holding pellet food and drinking water in bottle with stainless steel sipper tube. Each cage contained 6 rats. All rats had free access to potable water and standard pelleted laboratory animal diet *ad libitum*. Paddy husk was used as bedding material. The animals were divided into 5 groups (6 rats/group). Localized inflammatory pain was induced in all groups of animals by intraplantar injection of carrageenan (50 µl of 3% suspension).

One day before the experiment, three basal readings of hind paw in each rat were recorded. Group 1 received vehicle orally, Group 2 received a standard drug Diclofenac

sodium (10 mg/kg i.p), whereas groups 3,4and 5 received **KUSTATHI CHOORNAM**. The doses of **KUSTATHI CHOORNAM** were prepared **with HOT WATER**, whereas Diclofenac sodium was dissolved in normal saline. After 30 min, the rats were challenged with subcutaneous injection of 0.1 ml of 1% w/v solution of carrageenan into the sub plantar region of left paw. The paw was marked with ink at the level of lateral malleolus and immersed in mercury up to the mark. The paw volume was measured at 0, 1, 2, 3, 4, 5 and 6^{th} hr after carrageenin injection using Digital Plethysmometer. The difference between initial and subsequent reading gave the actual edema volume.

CONVERSION FORMULA:

Human dose is 1000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

1000 mg x 2(a) x 0.018 (b) = 18 (c) /150 gm of Rat

18/1000x150 = 2.7 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	2.7 mg /kg	1 ml
3	Middle Dose	13.5mg/kg	1 ml
4	High Dose	67.5mg/kg	1 ml

EXPERIMENTAL DESIGN:

Group-I: Served as a negative control (0.1ml of 1% carrageenin)

Group-II: Served as standard received Diclofenac sodium (10mg/kg, i.p) +

(0.1ml of 1% carrageenin)

Group-III: Received **KUSTATHI CHOORNAM** were prepared **with HOT WATER**

(2.7 mg /kg) + (0.1ml of 1% carrageenin)

Group IV: Received **KUSTATHI CHOORNAM** were prepared **with HOT WATER**

(13.5 mg/kg) + (0.1ml of 1% carrageenin)

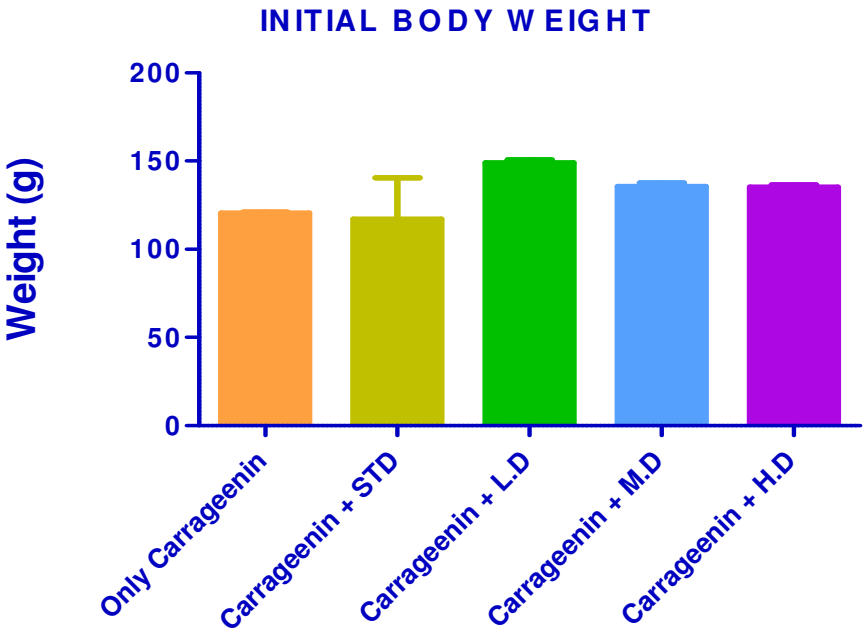
Group V: Received **KUSTATHI CHOORNAM** were prepared **with HOT WATER**

(67.5 mg/kg) + (0.1ml of 1% carrageenin)

TABLE: EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON Carrageenin -INDUCED PAW EDEMA IN RATS (BODY WEIGHT in gms)

Group	Only Carrageenan	Carrageenan+ Diclofenac 10mg/kg	Carrageenan+ L.D	Carrageenan +M.D	Carrageenan+H.D
INITIAL BODY WEIGHT	120.667± 0.3333	117.167± 2.4441	149± 1.67332	135.5± 2.09364	135.333± 1.22927

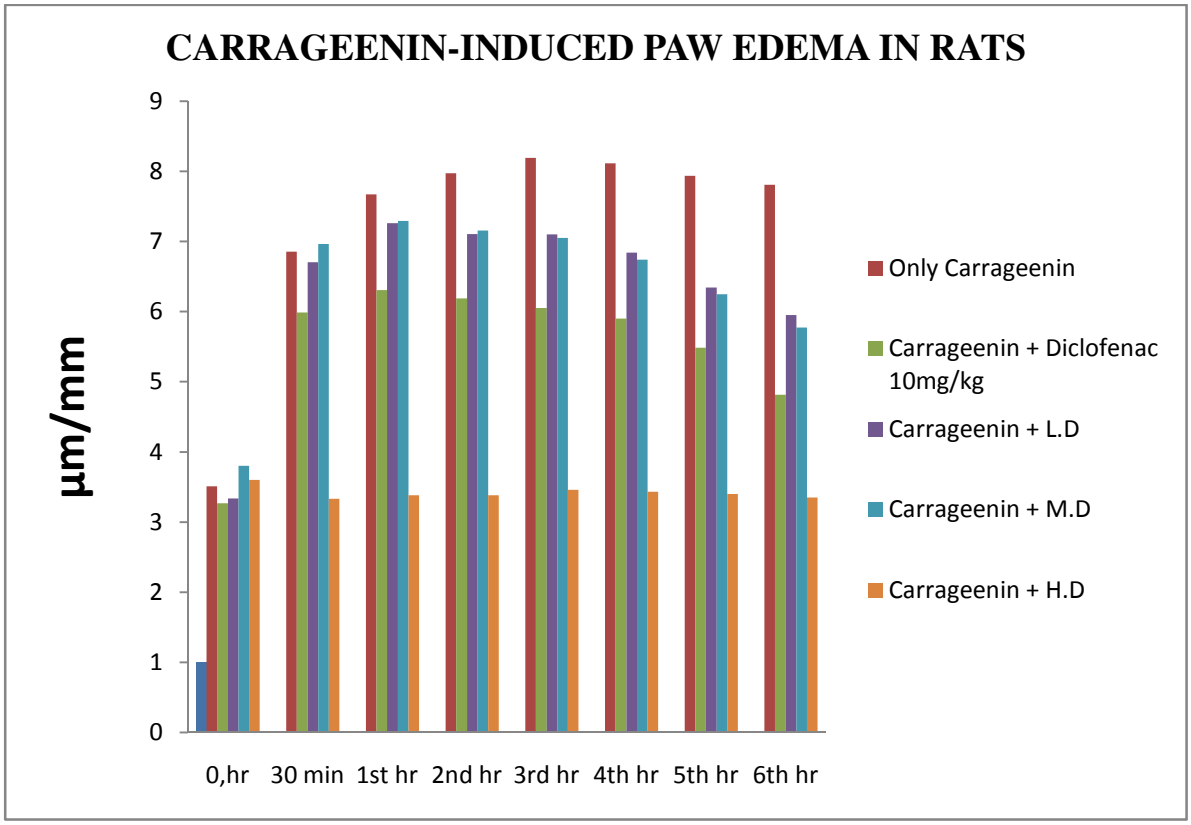
Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group


INITIAL BODY WEIGHT
Weight (g)
200
150
100
50
0
Only Carrageenin
Carrageenin + STD
Carrageenin + L.D
Carrageenin + M.D
Carrageenin + H.D

EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON Carrageenin - INDUCED PAW EDEMA IN RATS

Group	Mean paw volume before carrageenan injection	Paw Volume after induction with carrageenin Increase in paw volume (ml) after carrageenan injection (mean ± SEM)			Paw Volume after induction with carrageenin Increase in paw volume (ml) after carrageenan injection (mean ± SEM)			
	0 min	30 min	1hr	2hr	3h	4h	5h	6h
Only Carrageenan	3.51± 0.159812	6.85333 ± 0.152723	7.67333 ± 0.146394	7.97333 ± 0.168101	8.19± 0.16385	8.11333 ± 0.204527	7.935± 0.158109	7.81± 0.149644
Carrageenan + Standard	3.26667± 0.0670158	5.98667 ± 1.20647	6.30667 ± 1.27245	6.19± 1.24718	6.05± 1.22018	5.9± 1.18545 *	5.48667 ± 1.10041 *	4.81667 ± 0.973768**
Carrageenan + L.D	3.33667± 0.135982	6.70667 ± 0.106667	7.26167 ± 0.0817483	7.10667 ± 0.0616802	7.1± 0.0489898	6.84833 ± 0.0397003	6.34333 ± 0.0635435	5.95333 ± 0.0543241*
Carrageenan + M.D	3.8± 0.186619	6.965± 0.143428	7.29333 ± 0.148204	7.15667 ± 0.0716318	7.05333 ± 0.0660639	6.74333 ± 0.0873944	6.25± 0.0616982	5.77333 ± 0.0860491*
Carrageenan + H.D	3.60333± 0.120268	3.33167 ± 0.0283334	3.38± 0.0734393	3.385± 0.037036	3.46333 ± 0.0484883	3.43167 ± 0.0878034	3.40333 ± 0.0689283	3.35333 ± 0.0313759

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group.

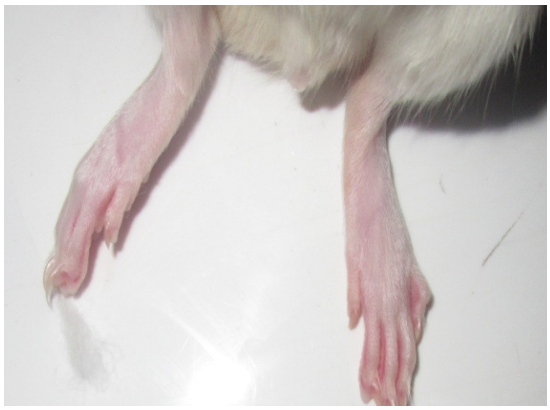

CARRAGEENIN-INDUCED PAW EDEMA IN RATS
µm/mm
9
8
7
6
5
4
3
2
1
0
0,hr
30 min
1st hr
2nd hr
3rd hr
4th hr
5th hr
6th hr
Only Carrageenin
Carrageenin + Diclofenac 10mg/kg
Carrageenin + L.D
Carrageenin + M.D
Carrageenin + H.D

EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON Carrageenin - INDUCED PAW EDEMA IN RATS

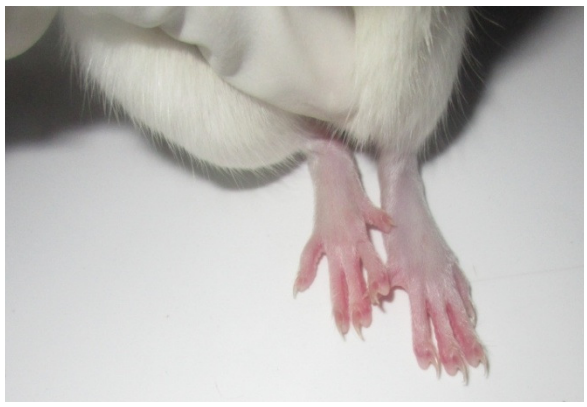
Only Carrageenin

Carrageenin+ STD

Carrageenin + L.D



Carrageenin + M.D



EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON ACETIC ACID INDUCED WRITHING IN MICE[1]

1. Kaneria MS, Naik SR, Kohli RK. Anti-inflammatory,antiarthritic and analgesic activity of a herbal formulation. Indian J.Experimental Biol. 2007; 45: 279.

Acetic acid induced writhing method was adopted for evaluation of analgesic activity. Writhing is defined as a stretch, tension to one side, extension of hind legs, contraction of the abdomen so that the abdomen of mice touches the floor, turning of trunk (twist). Any writhing is considered as a positive response.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

DRUGS:

Acetic acid (Sigma Chemical Co. Bangalore, India) and Indomethacin were purchased from (Ranbaxy, India). All drugs were dissolved in saline. The different doses of **KUSTATHI CHOORNAM** were prepared **WITH HOT WATER**.The control group received vehicle as control. All drugs were prepared just before use.

PREPARATION OF ACETIC ACID:

A solution of acetic acid (1% v/v) in distilled water was prepared.

CONVERSION FORMULA:

Human dose is 1000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 30 gm of Mice

1000 mg x 2(a) x 0.018 (b) = 18 (c) /30 gm of Mice

18/1000x30 = 0.54 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	0.54 mg /kg	1 ml
3	Middle Dose	2.7mg/kg	1 ml
4	High Dose	13.5mg/kg	1 ml

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL (IP injection of 0.1 ml 1% acetic acid)

GROUP 2 -- IP injection of 0.1 ml 1% acetic acid + Indomethacin (5mg/kg, i.p)

GROUP 3 -- 0.1 ml 1% acetic acid (ip) + KUSTATHI CHOORNAM WITH HOT WATER **0.54MG /KG(PO)**

GROUP 4 -- 0.1 ml 1% acetic acid (ip) + KUSTATHI CHOORNAM WITH HOT WATER **2.7mg/Kg(Po)**

GROUP 5 -- 0.1 ml 1% acetic acid (ip) + KUSTATHI CHOORNAM WITH HOT WATER 13.5mg/kg(po)

PROCEDURE:

Wister albino mice of either sex were divided into five different groups each containing Six animals, the animals were marked individually. Food was withdrawn 12 hours prior to drug administration till completion of experiment. The animals were weighed and numbered appropriately. The test and standard drugs were given orally. After 60 minutes writhing was induced by intra-peritoneal injection of 1% acetic acid in volume of 0.1 ml/10g body weight. The writhing episodes were recorded for 30 minutes; stretching movements consisting of arching of the back, elongation of body and extension of hind limbs were counted.

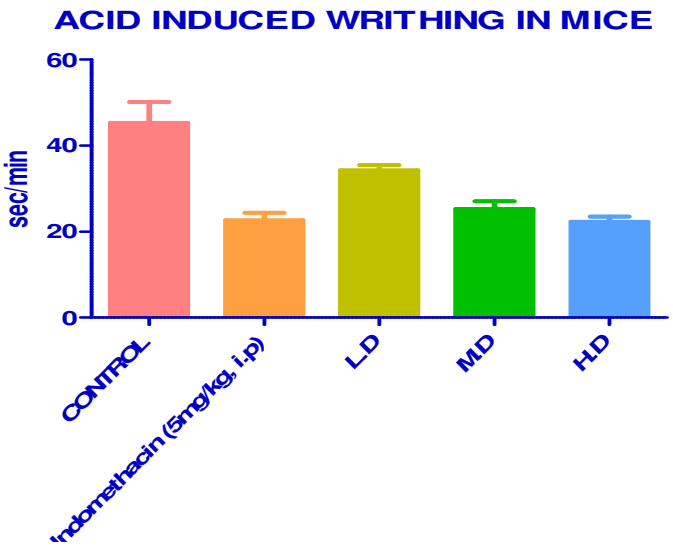
Anti-nociceptive activity was expressed as the percentage inhibition of abdominal constrictions using the ratio:

(Control mean – Treated mean) × 100/Control mean

EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON ACETIC ACID INDUCED WRITHING IN MICE[1]

GROUP	No of Writhing (30min)	Inhibition (%)
CONTROL	45.33±4.807	---
Indomethacin (5mg/kg, i.p)	22.67±1.764***	49.98 %
K C 0.028mg/kg(po)	34.33±1.202**	24.26 %
K C 0.014mg/kg(po)	25.33±1.764***	44.12 %
K C 0.28mg/kg(po)	22.33±1.202***	50.73 %

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



EFFECT OF KUSTATHI CHOORNAM WITH HOT WATER ON HOT PLATE METHOD IN MICE[1]

1. Turner RA. Screening methods in pharmacology. In: Turner, R., Hebborn, P. (eds.). Academic press, New York. 1965; 100.

The paws of mice and rats are very sensitive to heat at temperatures which are not damaging the skin. The responses are jumping, withdrawal of the paws and licking of the paws.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

The hot plate, which is commercially available, consists of a electrically heated surface. The temperature is controlled for 55° to 56 °C. This can be a copper plate or a heated glass surface. The animals are placed on the hot plate and the time until either licking or jumping occurs is recorded by a stop-watch.

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL

GROUP 2 – Pentazocine (10mg/kg, I.P)

GROUP 3 -- KUSTATHI CHOORNAM WITH HOT WATER

0.54 mg /kg(po)

GROUP 4 – KUSTATHI CHOORNAM WITH HOT WATER

2.7mg/kg(po)

GROUP 5 -- KUSTATHI CHOORNAM WITH HOT WATER

13.5mg/kg(po)

PROCEUDRE:

Mice were screened by placing them on a hot plate maintained at 55±1ºC and recording the reaction time in seconds for forepaw licking or jumping. Only mice which reacted within 15sec and which did not show large variation when tested on four separate occasions, each 15min apart, were taken for the test. The time for forepaw licking or jumping on the heated plate of the analgesiometer maintains at 55ºC was taken as the reaction time. Prior to treatment, the reaction time of each mouse (licking of the forepaws or jumping response) was done at 0- and 10-min interval. The average of the two readings was obtained as the initial reaction time (*Tb*). The reaction time (*Ta*) following the administration of the ----------, Pentazocine and distilled water was measured at 0.5, 1, 2, and 3h after latency period of 30min.

The following calculation was:

Percentage analgesic activity = $Ta\text{-}Tb/Tb \times 100$

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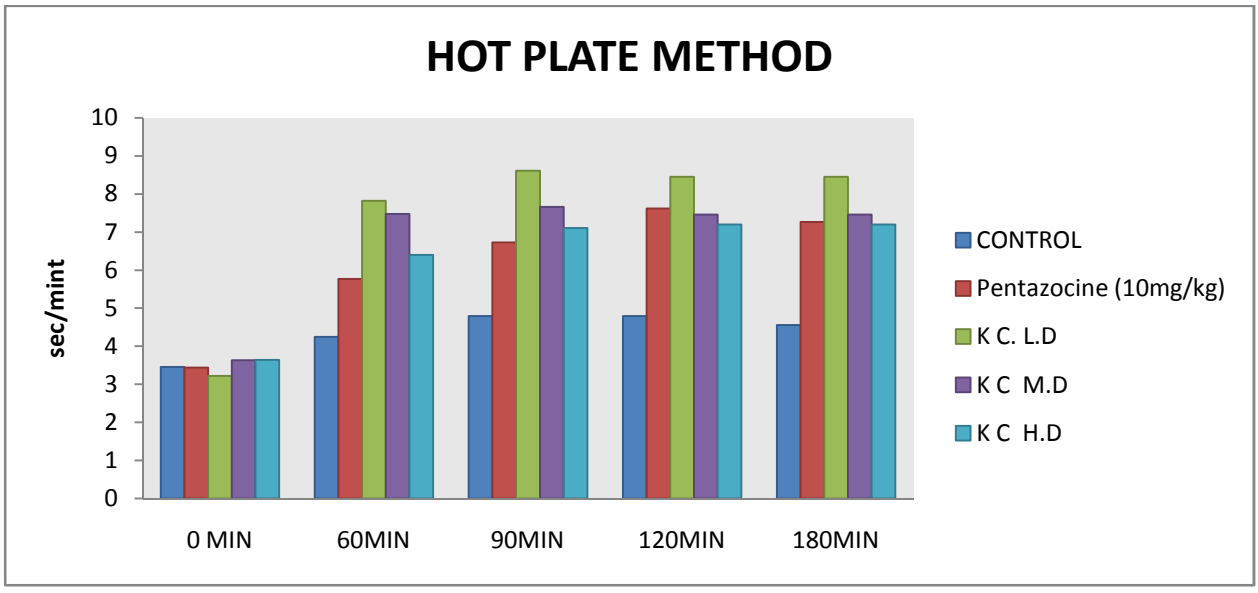
GROUP	Reaction time in seconds at time (minutes) (mean ± sem) (mean ± sem)				
	O mints	60 mints	90 mints	120 mints	180 mints
CONTROL	3.467±0.09333	4.257±0.196	4.793±0.096	4.77±0.121	4.56±0.193
STANDARD	3.447±0.1299	5.773±0.0693	6.737±0.210	7.62±0.150	7.27±0.206
K C + LOW DOSE	3.223±0.02028	7.83±0.0874	8.61±0.167	8.59±0.2401	8.45±0.0779
K C + MIDDLE DOSE	3.637±0.05783	7.48±0.1021	7.66±0.165	7.67±0.176	7.47±0.187
K C + HIGH DOSE	3.643±0.1943	6.4±0.1528	7.113±0.119	7.2±0.1041	7.20±0.223

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's $^{***}P< 0.001$, $^{**}P < 0.01$, $^{*}P < 0.05$ calculated by comparing treated group with CONTROL group.



ACUTE TOXICITY STUDY IN FEMALE WISTER RATS TO EVALUATE TOXICITY PROFILE OF KUSTATHI CHOORNAM WITH HOT WATER

Table 1. Test substance details

Name of the test substance	**KUSTATHI CHOORNAM WITH HOT WATER**
Colour of the test substance	BROWN
Nature of the test substance	Powder

Table 2. Experimental protocol

Name of the study	Acute toxicity
Guideline followed	OECD 423 method-acute toxic class method
Animals	Healthy young adult female wister rats, nulliparous, non-pregnant
Body weight	150-200 g
Sex	female
Administration of dose and volume	2000 mg/kg in 200g body weight, single dose in 1 ml
Number of groups and animals	5 groups and 3 animals in each group 100mg,250mg,500mg,1000mgand 2000mg/kg
Route of administration	Oral Cavage (po)
Vehicle	Hot Water

Table3. Housing and feeding conditions

Room temperature	22°C ± 3°C
Humidity	40-60%
Light	12 h : 12h (light : dark cycle)
Feed	Standard laboratory animal food pellets with water *ad libitum*

Table 4. Study period and observation parameters

Initial once observation	First 30 minutes and periodically 24 h
Special attention	First 1-4 h after drug administration
Long term observation	Upto 14 days
Direct observation parameters	Tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
Additional observation parameters	Skin and fur, eyes and mucous membrane, respiratory, circulatory, autonomic and central nervous systems, somato motor activity and behavior pattern etc.

The time of death, if any, is recorded. (Complete observations: annexure I). After administration of the drug, food is withheld for a further 1-2 hours.

Study procedure

Acute oral toxicity was performed as per organization for economic co-operation for development (OECD) guideline 423 method. The **KUSTATHI CHOORNAM with HOT WATER** was administered in a single dose by tuberculin syringe. Animals are fasted 3 h prior to dosing (food was withheld for 3 h but not water). Following the period of fasting animals was weighed and test substance was administered orally at a dose of 100mg,250mg,500mg,1000mgand 2000mg/kg. After the **KUSTATHI CHOORNAM with HOT WATER** administration, food was withheld 2 h in mice. Animals are observed individually after at least once during the first 30 minutes, periodically during the first 24 hrs, with special attention given during the first 4 hrs, and daily thereafter, for a total of 14 days.

REPORT

Toxicological evaluation of KUSTATHI CHOORNAM with HOT WATER

Table:5 Effect of **KUSTATHI CHOORNAM with HOT WATER** on acute toxicity test in female rats.

S.N	Response	Head		Body		Tail	
		Before	After	Before	After	Before	After
1	Alertness	Normal	Normal	Normal	Normal	Normal	Normal
2	Grooming	Absent	Absent	Absent	Absent	Absent	Absent
3	Touch response	Absent	Absent	Absent	Absent	Absent	Absent
4	Torch response	Normal	Normal	Normal	Normal	Normal	Normal
5	Pain response	Normal	Normal	Normal	Normal	Normal	Normal
6	Tremors	Absent	Absent	Absent	Absent	Absent	Absent
7	Convulsion	Absent	Absent	Absent	Absent	Absent	Absent
8	Righting reflux	Normal	Normal	Normal	Normal	Normal	Normal
9	Gripping strength	Normal	Normal	Normal	Normal	Normal	Normal
10	Pinna reflux	Present	Present	Present	Present	Present	Present
11	Corneal reflux	Present	Present	Present	Present	Present	Present
12	Writhing	Absent	Absent	Absent	Absent	Absent	Absent
13	Pupils	Normal	Normal	Normal	Normal	Normal	Normal
14	Urination	Normal	Normal	Normal	Normal	Normal	Normal
15	Salivation	Normal	Normal	Normal	Normal	Normal	Normal
16	Skin colour	Normal	Normal	Normal	Normal	Normal	Normal
17	Lacrimation	Normal	Normal	Normal	Normal	Normal	Normal

RESULT:

From acute toxicity study it was observed that the administration of **KUSTATHI CHOORNAM with HOT WATER** to Female Wister rats did not induce drug-related toxicity and mortality in the animals up to 2000mg/kg in 200g female Wister rats. So No-Observed-Adverse-Effect- Level (NOAEL) of **KUSTATHI CHOORNAM with HOT WATER** is 2000 mg/kg equal to human dose

DISCUSSION

KUSTATHI CHOORNAM with HOT WATER was administered single time at the doses of 100mg, 250mg, 500mg, 1000mg and 2000mg/kg to female Wister rats and observed for consecutive 14 days after administration. Doses were selected based on the pilot study and literature review. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded. No mortality was observed during the entire period of the study. Data obtained in this study indicated no significance physical and behavioral signs of any toxicity due to administration of **KUSTATHI CHOORNAM with HOT WATER** at the doses of 100 mg, 250mg ,500mg, 1000mg and 2000mg/kg to female Wister rats

At the 14th day, all animals were observed for functional and behavioral examination. In functional and behavioral examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, Clonic involuntary movement, Tonic involuntary movement, Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities like Reactivity, Handling, Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioral examination was normal in all treated groups. Food consumption of all treated animals was found normal as compared to normal group.

SUMMARY & CONCLUSION:

Summary:

The present study was conducted to know single dose toxicity of **KUSTATHI CHOORNAM with HOT WATER** on female Wister rats. The study was conducted using 15 female Wister rats. The female animals were selected for study of 8- 12 weeks old with weight range of within ± 20 % of mean body weight at the time of randomization. The groups were numbered as group I, II, III, IV and V and dose with 100mg, 250mg, 500mg, 1000mg and 2000mg/kg of **KUSTATHI CHOORNAM with HOT WATER**. The drug was administered by oral route single time and observed for 14 days. Daily the animals were observed for clinical signs and mortality.

There were no physical and behavioral changes observed in Female Wister rats during 14 days. Mortality was not observed in any treatment groups.

Conclusion:

The study shows that **KUSTATHI CHOORNAM with HOT WATER** did not produce any toxic effect at dose of 100mg, 250mg, 500mg, 1000mg and 2000mg/kg to rats. So No-Observed-Adverse-Effect-Level (NOAEL) of **KUSTATHI CHOORNAM with HOT WATER** is 2000 mg/kg.

7.0 ABBREVIATIONS

No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o	peros
ML	Milliliter
%	percentage
R&D	Research and Development
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level
MLD	Minimum Lethal Dose
MTD	Maximum Tolerated Dose
OECD	Organisation of Economic Co-operation and Development
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals

8.0 REFERENCES:

1. OECD. Guideline for Testing of Chemicals 423, Acute oral toxicity (acute toxic class method). December 2001.

SUB-ACUTE TOXICITY STUDY IN WISTER RATS TO EVALUATE TOXICITY PROFILE OF KUSTATHI CHOORNAM WITH HOT WATER

Objective

The objective of this study is to evaluate the toxic effects, if any, as a result of the repeated once daily oral administration of **KUSTATHI CHOORNAM WITH HOT WATER** to Wister Albino rats for a minimum period of 28 consecutive days. This study will provide information on any major toxic effects, target organs and a rationale for concluding the No-Observed-Adverse-Effect-Level (NOAEL) and/or No Observed Effect Level (NOEL) / LOEL (Low Observed Effect Level) and risk assessment in humans.

1. Test Guidelines

This study plan is prepared as per the following guidelines:

Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

OECD – 407 – Repeated dose 28-day Oral Toxicity Study in Rodents, Adopted 3 October, 2008.

1.1. Test System Details

Species	:	Rat
Strain	:	Wister Albino
Source	:	Sree Venkateshwara Enterprises Pvt Ltd, Bangalore
Age	:	6-8 weeks
Sex	:	Male / Female (nulliparous and non-pregnant)
Body weight	:	160.0to 180.0 g

1.2. Acclimatization

Animals will be allowed to acclimatize to the experimental room conditions for five days prior to the commencement of dosing. During the acclimatization period, the animals will be observed daily for any apparent adverse clinical signs. Prior to assignment to the study and commencement of treatment, a detailed physical health examination will be performed on all animals by a veterinarian and animals with any evidence of ill health or poor physical condition will not selected for the study.

1.3. Randomization and Grouping

On the starting day of dosing, the animals will be weighed and health examination will be performed by veterinarian. Animals will be randomly allocated to different groups according to their body weight by using MS-Excel sheet as described in the randomization SOP. Animals will be divided into four groups (vehicle control, low, intermediate, and high dose). At the initiation of the treatment, the body weight variation between the groups did not exceed ±20% of the mean weight of each sex.

1.4. Animal Identification

In each cage, animals will be identified with numbers by marking at the base of the ear. The cages will be identified with an attached colored cage label showing study number, study code, group number, sex, dose, strain, species, cage number, route of administration and animal number.

2. Animal Husbandry

2.1. Animal Welfare and approval

The study was approved by the IAEC (SLS) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA registration number: Abc14).Their recommendations regarding animal care and handling will be followed.

2.2. Environmental Conditions

The temperature of the experimental room will be maintained at 22 ± 3^{0}C and the relative humidity between 30-70 %. The photoperiod will be 12 hours light and 12 hours dark cycles

2.3. Housing Conditions

Two animals will be housed in autoclaved polypropylene rat cages (Size in mm=L x W x H: 430 x 290 x 160) using paddy husk as the bedding material. Each cage will be fitted with a top grill having provision for keeping rodent pellet feed and an autoclaved polypropylene water bottle with stainless steel drinking nozzle. Cages will be placed on 3-tier racks and cage rotation will be performed every week. Cages will be changed at least twice a week. The cages and water bottles will be cleaned and autoclave sterilized.

2.4. Sanitation

Each day, the floor of the animal room will be swept and mopped. Cages and bedding material will be changed once in three days and water bottles will be changed daily. All the experimental procedures will be done in a clean environment.

2.5. Feed

The experimental animals will be provided with irradiated rodent pellet feed *ad libitum* supplied from Sai feeds Pvt ltd, Chennai . Feed will be withheld for four hours prior to blood collection and necropsy.

2.6. Drinking Water

Animals will be provided with filtered drinking water *ad libitum* passed through water filter system (Aquaguard™) in autoclaved polypropylene bottles. Water bottles will be changed daily. Microbial analysis of water will be carried out once monthly and the report is maintained in the study file.

3. Personnel Safety

All personnel handling animals undergo regular medical examination. Protective clothing like apron, face mask, head cap, and gloves will be used to maintain hygienic conditions.

4. Materials and Methods

4.1. Preparation of Dose formulation

The dose formulation will be prepared under aseptic conditions as per SLS, SOP.

4.2. Route of Administration and Justification

Administration will be by oral gavage, as it is one of the possible routes of exposure.

4.3. Frequency and Duration of Administration

Once daily for 28 consecutive days

4.4. Dosing Procedure

The test item will be administered in once daily by oral gavage using a suitable intubation cannula fitted with a graduated syringe. The scheme of dosing and sacrifice time points are presented in the below below Table.

4.5. Experimental Procedures

All experimental procedures will be performed in accordance with the Study plan and Standard Operating Procedures (SOPs) of SLS.

CONVERSION FORMULA:

Human dose is 1000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

1000 mg x 2(a) x 0.018 (b) = 18 (c) /150 gm of Rat

18/1000x150 = 2.7 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	2.7 mg /kg	1 ml
3	Middle Dose	13.5mg/kg	1 ml
4	High Dose	67.5mg/kg	1 ml

Experimental Design

Group No.	Group	Dose (mg/kg b.wt /day)	No. of Animals	
			Male	Female
G1	Vehicle control	**HONEY/GHEE**	5	5
G2	Low dose of **KUSTATHI CHOORNAM WITH HOT WATER**	2.7mg/kg	5	5
G3	Intermediate dose **KUSTATHI CHOORNAM WITH HOT WATER**	13.5mg/kg	5	5
G4	High dose **KUSTATHI CHOORNAM WITH HOT WATER**	67.5mg/kg	5	5

5. Observations

Animals will be observed daily throughout the treatment period at regular intervals. During the treatment period, animals will be observed twice daily for any clinical signs of toxicity, morbidity and mortality. All the surviving animals will be sacrificed at the end of scheduled period and subjected to gross necropsy and histopathological evaluations.

5.1.Clinical Signs

All the animals will be subjected to cage-side (home-cage) observations twice a day for any clinical signs of toxicity, preferably at the same time each day and considering the peak period of anticipated effect. In addition to home cage observations, a detailed clinical examination will be performed once prior to dosing and weekly thereafter during treatment period.

5.2. Morbidity/ Mortality

All animals will be examined twice a day for mortality and signs of morbidity.

5.3. Body Weights

Body weights will be recorded at the beginning of acclimatization, before randomization, there after at weekly intervals and at the time of necropsy.

5.4. Feed Consumption

Feed consumption will be calculated on a weekly basis throughout the study period.

5.5. Hematology and Clinical Biochemistry

Hematology and clinical biochemistry tests will be performed with terminally collected blood samples on day-29 from all animals. Animals will be deprived of feed overnight and blood samples will be collected by tapping the ear for visibility of the vein site and inserted the needle into the marginal ear vein and collected the blood into micro centrifuge tube. Approximately 0.5 ml of blood will be collected in vials containing 1% EDTA (20µl) as an anticoagulant for hematological analysis.

Approximately 2 ml blood will be collected from each animal in micro centrifuge tubes containing 15µl of heparin (19 units) and the plasma will be separated by

centrifugation at 4000 rpm for ten minutes at 4^{o}C. The plasma will be stored at -20 ^{o}C ± 2 and used for all clinical chemistry analysis.

5.6. Hematology

Erythrocyte count (RBC), Total Leucocyte count (WBC), Hemoglobin (Hb), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Platelet (PLTC).

5.7. Clinical Biochemistry

Glucose, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline phosphatase (ALP), Total protein, Albumin, Creatinine, Urea, Cholesterol, Triglycerides, Sodium, Potassium, Calcium, and Chloride.

5.8 Pathology

All animals will be euthanized by CO_2 asphyxiation and subjected to necropsy under the supervision of the veterinary pathologist. Different tissues/organs of thoracic, abdominal and cranial cavities will be examined for any gross pathological changes. Tissues from vehicle control and high dose groups will be subjected to detailed histopathological analysis (Ovaries/ testes, kidneys, liver, lungs). The organs will be fixed using Bouin's (reproductive organs) and 10% neutral buffered formalin (kidneys, liver, spleen, lungs).Processing of tissue will be done by spin tissue processer, embedding of the tissue by tissue embedder. The tissues will be initially trimmed to 10-20µ thickness and later 3-6µ to obtain thinner tissue sections by using rotary microtome. Haematoxylin and Eosin staining will be performed for all tissues.

5.8. Organ Weights

Absolute weights of adrenal glands, brain, ovaries/testes, epididymis/uterus, heart, kidneys, liver, spleen and lungs will be recorded for all the animals after trimming adherent tissue immediately after dissection from the animal. Paired organs will be weighed together. Relative weights of these organs against fasting animal body weights will be calculated and reported.

6. Data Compilation

Data will be summarised in a tabular form showing the number of animals, experimental design, dose groups, dose volume and concentrations, test item and vehicle control details. All findings like clinical signs, mortality and morbidity data, time of death, body weights, feed consumption, clinical signs, and necropsy and pathology observations will be recorded and given in the final report. One original copy of the final report is issued to the sponsor.

7. Statistical Analysis

All the parameters of treated groups of both sex, viz. body weight, feed consumption, organ weights (absolute and relative), biochemical parameters, and hematology parameters will be analyzed using SPSS software, version 16.0 by using one-way ANOVA test with multiple comparison (vehicle controls treated groups) in the study report, and p value < 0.05 is considered as statistically significant.

8. References

1. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for Laboratory Animal Facility, The Gazette of India, 1998.
2. Hayes AW, 2000. Principles and Methods of Toxicology, 4th ed., Taylor and Francis, London.
3. Karl-Heinz Diehl, R. H. (2001). A Good Practice Guide to the Administration of Substances and Removal of Blood, Including Routes and Volumes. journal of applied toxicology , 15-23.
4. OECD – 407 - Repeated dose 28-day oral Toxicity Study in Rodents, Adopted October 3, 2008.
5. Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

MATERIALS AND METHODS

ESTIMATION OF HEMATOLOGICAL PARAMETERS: [1]

Collection of blood for hematological studies

After the treatment period the animals were anaesthetized by ketamine hydrochloride and the blood was collected from Retro-orbital sinus by using capillary into a centrifugation tube which contains EDTA for haematological parameters The haematological parameters like RBC, WBC and Hb percentage, Differential cell count, MCV, MCHC, Hematocrit, MCH, platelet count were estimated by the following procedures.

1. ENUMERATION OF RED BLOOD CELLS: [1] Ramnic 2007)

Reagents : RBC diluting fluid

Procedure:

Using a red blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and RBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried. Using 45X or high power objective the RBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells $x10^{12}/l$

2. ENUMERATION OF WBC: [2] John 1972)

Reagents:

Turk's fluid: Turk's fluid was prepared by mixing 2ml of acetic acid with 100 ml of distilled water. To this 10 drop of aqueous methylene blue 3 % w/v) was added. This solution haemolysis the red cells due to acidity so that counting of white cells becomes easy.

Procedure:

Using a white blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and WBC diluting fluid was taken up to mark II. The fluid blood

mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried.

Using 10X or low power objective the WBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells/10mm.

3. DIFFERENTIAL LEUCOCYTE COUNT: [3] John 1972)

Reagent:

Leishmann's stain: 150mg of powdered leishmann's stain was dissolved in 133ml of acetone free methanol.

Procedure:

A blood film stained with leishmann's stain was examined under oil immersion and the different types of WBCs were identified. The percentage distribution of these cells was then determined. Smears were made from anticoagulant blood specimens and stained with leishmann's stain. The slides were preserved for counting the number of lymphocytes and neutrophils, per 100 cells were noted.

From the different Leukocyte count and WBC count, absolute lymphocyte and neutrophil count were calculated.

$$\text{Absolute neutrophil count} = \frac{\text{Number of neutrophils}}{100} \times \text{TWBC}$$

$$\text{Absolute lymphocyte count} = \frac{\text{Number of lymphocytes}}{100} \times \text{TWBC}$$

DETERMINATION OF BIOCHEMICAL PARAMETERS:

For assessment of biochemical parameters, blood samples were collected from the animals by puncturing the retro-orbital plexus and centrifuged. The serum collected after centrifugation was analyzed for various biochemical parameters like SGOT, SGPT, ALP,TC.TG,HDL All of the above biochemical parameters were estimated using semi autoanalyzer (Photometer 5010 $_{V5+}$, Germany) with enzymatic kits procured from Piramal Healthcare limited, Lab Diagnostic Division, Mumbai, India.

1. Total Cholesterol (TC)

Principle

Determination of cholesterol is done after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (trinder's reaction).

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{CHE}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{CHO}} \text{Cholesterol-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinonelimine} + 4\ H_2O_2$$

Method

CHOD-PAP: Enzymatic photometric test

Table 6: Reagents

Goods buffer (pH 6.7)	50 mmol/ l
Phenol	5 mmol/l
4-aminoantipyrine	0.3 mmol/l
Cholesterol estrase	> 200 U/l
Cholesterol oxidase	> 100 U/l
Peroxidase	3 KU/l
Standard	(5.2 mmol/l)

Assay procedure

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 5 min.
d. Read the test sample.

NORMAL RANGE: < 200 mg/dl in serum.

1. Deeg R, Ziegenhorn J, Kinetic enzymatic method for automated determination of total cholesterol in serum, Clin. Chem., 1983, 29:1798-802.

2. Triglycerides

Principle

Determination of triglycerides (TG) alters enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine which is generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxidase under the catalytic action of peroxidase.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol + fatty acid}$$

$$\text{Glycerol + ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate+ ADP}$$

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyaceton phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine + 4- chlorophenol} \xrightarrow{\text{POD}} \text{Quinonelimine + HCL} + 4H_2O_2$$

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO).

Reagents

Components and concentrations in the test Goods buffer pH 7.2, 50 mmol/ l

Table 7: Reagents

4-chloroPhenol	4 mmol/l
ATP	2 mmol/l
Mg^{2+}	15 mmol/l
Glycerokinase	> 0.4 Kμ/l
Peroxidase	> 2 Kμ/l
Lipoprotein lipase	> 4 Kμ/l
4-aminoantipyrine	0.5 mmol/l
Glcerol-3-phosphate- oxidase	> 1.5Kμ/l
Standard	(2.3 mmol/l)

Assay procedure

a. 1 ml (1000 μl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 μl) of serum.
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: < 200 mg/dl in serum.

1. Cole T.G, Klotzsch S.G, Mcnarmara J, Measurement of triglyceride concentration, In Rifai N, Warnick G.R, Dominiczak M.H, Handbook of lipoprotein testing, Washington:AACC, Press, 1997, 115-26.

3. HDL Cholestrol

Principle

Chylomicrons, VLDL and LDL are precipitated by adding phosphotungstic acid and magnesium ions to the sample. Centrifugation leaves only the HDL in the supernatant. The cholesterol content in it is determined enzymatically.

Method

Phosphotungstic acid precipitation method.

Table 8: Reagents

Phosphotungstic acid	0.55 mmol/l
Magnesium chloride	25 mmol/l

Assay procedure

A. Preparation of supernatant for the HDL-CHL estimation

Added 200 µl of serum to the 500 µl of HDL-Cholesterol precipitating reagent (from HDL kit) in 1.5 ml centrifuge tube and mixed well. Centrifuged the above solution at 4000 rpm for 10 min.

B. Preparation of test sample for the estimation of HDL-Cholesterol

a. Taken 1000 µl of reagent-1 (from cholesterol kit) in a 5 ml test tube.
b. Added, 100 µl of supernatant from above centrifuged solution
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: > 60 mg/dl in serum.

1. Friedewald W.T, Levy R.T, Frederickson D.S, Estimation of VLDL and LDL cholesterol, Clin. Chem., 1972, 18:499-502.

4. ESTIMATION OF SERUM GLUTAMATE PYRUVATE TRANSAMINASES (SGPT/ ALT)

1. Determination of aspartate aminotransferase (AST)

Aspartate aminotransferase, also known as Glutamate Oxaloacetate Transaminase (GOT) catalyses the transamination of L-aspartate and α keto glutarate to form oxaloacetate and L- glutamate. Oxaloacetate formed is coupled with 2,4- Dinitrophenyl hydrazine to form hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered aspartate (pH 7.4); 2,4- DNPH reagent; 4N sodium hydroxide; working pyruvate standard; solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was adopted for the estimation of SGOT. (Reitmann S, Frankel S, 1957. A colorimetric method for the determination of serum oxaloacetic and glutamic pyruvate transminases. American Journal of Clinical Pathology.28: 56-63.The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered aspartate was added into all the test tubes. Then 0.05 ml of serum was added to the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at $37^{o}C$ for 60 min, after which 0.25 ml each of 2,4-DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution I was added to all test tubes. Mixed properly and optical density was measured in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:-

AST (GOT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard

2. Determination of alanine aminotransferase (ALT)

Alanine aminotransferase, also known as Glutathione Peroxidase (GPT) catalyses the transamination of L-alanine and α keto glutarate to form pyruvate and L- Glutamate. Pyruvate so formed is coupled with 2,4 – Dinitrophenyl hydrazine to form a corresponding hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered alanine (pH 7.4), 2,4–DNPH, 4N sodium hydroxide, working pyruvate standard, solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was dopted for the estimation of SGPT. The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered alanine was added into all the test tubes. This was followed by the addition of 0.05 ml of serum into the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37^{o}C for 60 minutes, after which 0.25 ml each of 2,4-DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution **I** was added to all test tubes. Mixed properly and optical density was read against purified water in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:- ALT (GPT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard.

3. Determination of alkaline phosphatase (ALP)

Alkaline phoshatase from serum converts phenyl phosphate to inorganic phosphate and phenol at pH 10.0. Phenol so formed reacts in alkaline medium with 4-aminoantipyrine in presence of the oxidising agent potassium ferricyanide and forms an orange-red coloured complex, which can be measured spectrometrically. The color intensity is proportional to the enzyme activity.

Reagents:

Buffered substrate

Chromogen Reagent

Phenol Standard, 10 mg%

Procedure:

ALP was determined using the method of Kind (Kind PRM, King EJ, 1972. *In-vitro* determination of serum alkaline phosphatase. Journal of Clinical Pathology 7: 321-22\). The working solution was prepared by reconstituting one vial of buffered substrate with 2.2 ml of water. 0.5 ml of working buffered substrate and 1.5 ml of purified water was dispensed to blank, standard, control and test. Mixed well and incubated at 37^0C for 3 min. 0.05 ml each of serum and phenol standard were added to test and standard test tubes respectively. Mixed well and incubated for 15 min at 37^0C. Thereafter, 1 ml of chromogen reagent was added to all the test tubes. Then, added 0.05 ml of serum to control. Mixed well after addition of each reagent and the O.D of blank, standard, control and test were read against purified water at 510 nm.

Serum alkaline phosphatase activity in KA units was calculated as follows
[(O.D. Test-O.D. Control) / (O.D. Standard- O.D. Blank)] x 10

4. Determination of bilirubin

In toxic liver, bilirubin levels are elevated. Hyperbilirubinemia can result from impaired hepatic uptake of unconjugated bilirubin, such a situation can occur in generalized liver cell injury, certain drugs (e.g Rifampin and probenecid) interfere with the rat uptake of bilirubin by the liver cell and may produce a mild unconjugated

hyperbilirubinemia. Bilirubin level rises in diseases of hepatocytes, obstruction to bilirubin excretion into duodenum, in haemolysis and defects of hepatic uptake and conjugation of Bilirubin pigment such as Gilbert's disease.

Elevation of total serum bilirubin may occur due to:

1. Excessive haemolysis or destruction of the red blood cells.Eg:Haemolytic disease of the new born.
2. Liver diseases.Eg.Hepatitis and cirrhosis.
3. Obstruction of the biliary tract.Eg.Gall stones.

The method is based on the reaction of Sulfonilic acid with sodium nitrite to form azobilirubin which has maximum absorbance at 546nm in the aqueous solution. The intensity of the color Produced is directly proportional to the amount of direct or total bilurubin concentration present in the sample.

Reagents

1. Diazo A-(Reagent-R1) :Ready to use

2. Diazo B-(Reagent-R2):Ready to use

3. Bilirubin Activater :Ready to use

Procedure

Kind & King's method was followed for the estimation of Bilirubin. Five hundred µl of working reagent was added to 50 µl of rat serum & incubated for 5 min at 37°C. Absorbance was measured AT 546 NM in semi auto analyzer against the standard.

The Bilirubin content was calculated using the following equation:

Total bilirubin (mg/dt) = Abs of the sample blank x 15.

Direct Bilirubin(mg/dt) = Abs of sample blank x 10.

5. ESTIMATION OF UREA

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyper uremia or azotemia.

Method

Estimation of urea was done by Urease-GLDH: enzymatic UV test.

Principle

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4 + 2HCO_3$$

$$\text{2- Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L- Glutamate} + NAD^+ + H_2O$$

Table 14. Reagents

R 1	TRIS pH 7.8	120 mmol/l
	2-Oxoglutarate	7 mmol/l
	ADP	0.6 mmol/l
	Urease	≥ 6 KU/l
	GLDH	≥ 1 KU/l
R 2	NADH	0.25 mmol
R 3	Standard	40 mg/dl

Procedure

a. Take 1000 µl of reagent-1 and 250 µl of reagent-2 in 5 ml test tube.
b. To this, add 10 µl of serum.
c. Mix well and immediately read the test sample at 340 nm Hg 334 nm Hg 365 nm optical path 1 cm against reagent blank (2-point kinetic).
d. And note down the value.

Normal range: 10 – 50 mg/dl.

6. ESTIMATION OF URIC ACID

Uric acid and its salts are end products of the purine metabolism. In gout the most common complication of hyperuricemia, ie. Increased serum levels of uric acid lead to formation of monosodium urate crystal around the joints.

Method

Enzymatic photometric test using TOOS (N ethyl- N (hydroxyl -3- sulfopropyl)-m- toluidin)

Principle

Uric acid + H_2O + O_2 $\xrightarrow{\text{uricase}}$ Allantoin +CO_2 +H_2O_2

TOOS + 4 aminoantipyrine + $2H_2O_2$ $\xrightarrow{\text{POD}}$ Indamine + $3H_2O$

Table 15.reagents

R1	Phosphate buffer pH 7.0	100mmol/l
	TOOS	1mmol/l
	Ascorbate oxidase	≥1 KU/l
R2	Phosphate buffer pH 7.0	100mmol/l
	4- amino antipyrine	0.3mmol/l
	K_4 (Fe(CN)$_6$)	10µmol/l
	Peroxidase	≥1KU/l
	Uricase	≥50U/l

Procedure

a. Take 800µl of reagents -1 in a2ml centrifuge tube.
b. To this add 20µl of serum.
c. Mix well and incubate at 30°c for 5 minutes.
d. Then add 200µl of reagent2
e. Mix well incubate for 5min at 37°c
f. Measure the not down the values.

Normal range: 1.9-8.2mg/dl

7. ESTIMATION OF CREATININE:

Principle:

Creatinine forms a coloured complex with picrate in alkaline medium.

The rate of formation of the complex is measured.

Reagents:

Reagent 1 Standard Creatinine (2mg/100ml)

Reagent 2 Picric acid solution.

Reagent 3 sodium hydroxide solution

Procedure:

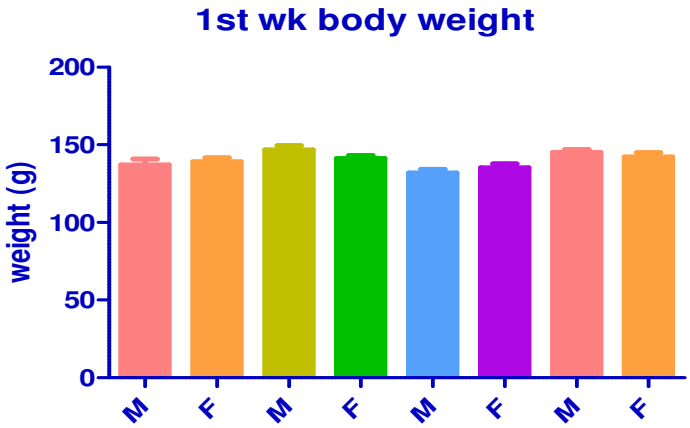
Take 500 µl of reagent -2 and 500 µl of reagent -3 in a 5ml test tube. To this add 100 µl of serum. Mix well and immediately read the test sample at Hg 492 nm 1cm light path and note down the values.

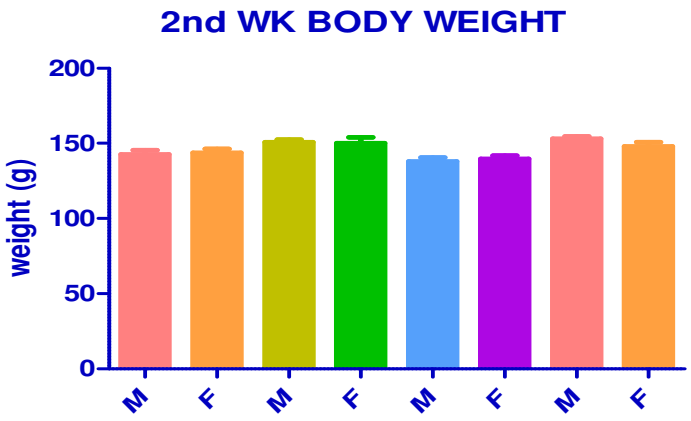
Normal range is 0.6 -1.1 mg/dl.

TABLE: 1 EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF KUSTATHI CHOORNAM WITH HOT WATER ON BODY WEIGHT IN Gram (PHYSICAL PARAMETER)

GPs	Control		Low Dose		Middle Dose		High Dose	
	Male	Female	Male	Female	Male	Female	Male	Female
1st wk	137.3±3.528	139.3±2.404	146.7±2.906	141.3±1.764	132±2.309	135.3±2.404	145.3±1.764	142.3±2.728
2nd wk	142.7±2.906	143.7±2.603	150.7±1.764	150±4.163	138±2.646	139.7±2.186	153±1.732	148±2.887
3rd wk	151.7±3.844	152±4	154±3.055	156.7±1.764	146.7±1.453	147.3±2.963	157±1.528	154.3±2.728
4th wk	162±2.082	162.7±3.528	163.3±3.48	166.3±0.8819	157.7±0.8819	158.7±2.603	166±2.082	162±2.646

Values are expressed as the mean ± S.D

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weight (g)
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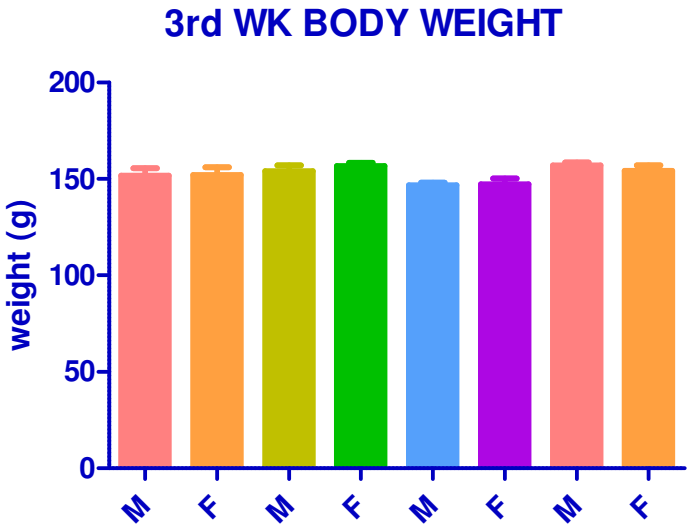
150
100
50
0
M
F
M
F
M
F
M
F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weight (g)
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150
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50
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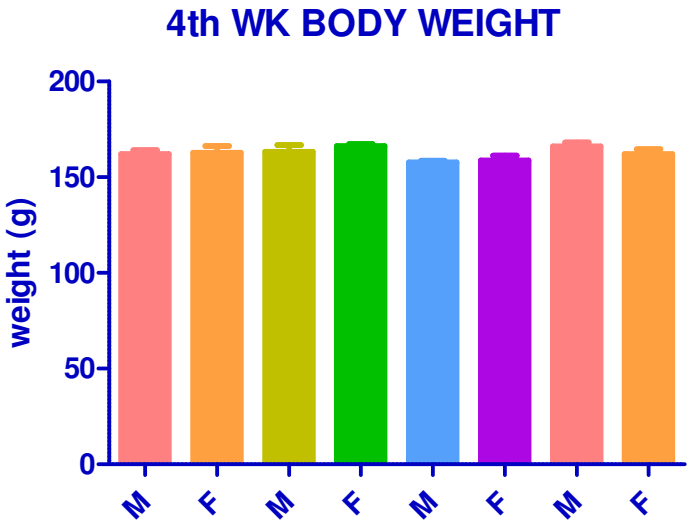
M
F
M
F
M
F
M
F

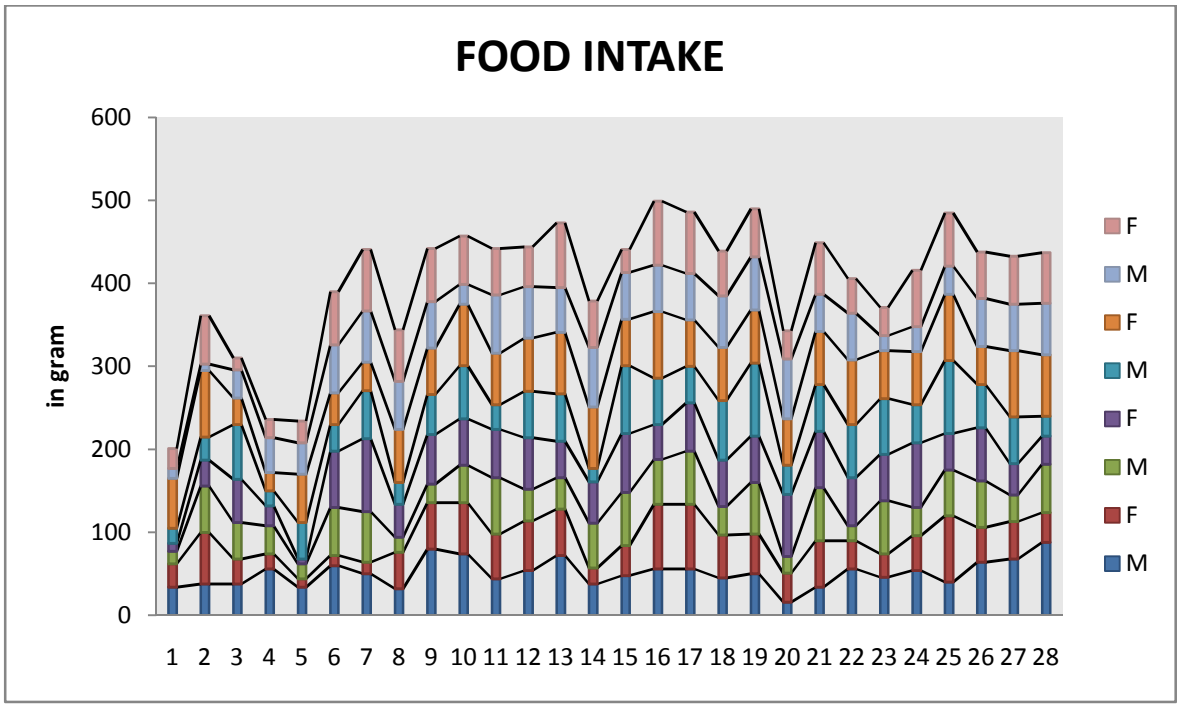

4th WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F

EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF KUSTATHI CHOORNAM WITH HOT WATER ON FOOD INTAKE In Gram

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	34	28	15	10	18	60	12	24
DAY2	38	62	56	31	28	80	8	58
DAY3	38	30	44	52	66	32	34	14
Day 4	56	18	34	24	18	22	42	22
DAY5	34	10	18	6	44	58	38	26
Day 6	60	12	58	68	32	38	58	64
DAY7	50	14	61	88	58	34	62	74
DAY8	32	44	18	40	26	64	58	62
Day 9	80	56	22	60	48	56	56	64
DAY10	74	62	45	56	64	74	24	58
Day 11	44	54	68	58	30	62	70	56
DAY12	54	60	38	62	56	64	62	48
DAY13	72	56	38	44	57	74	54	78
Day 14	38	19	54	50	16	74	72	56
DAY15	48	36	64	71	82	56	56	28
Day 16	56	78	54	42	56	80	56	77
DAY17	56	78	64	58	44	56	56	74
DAY18	45	52	34	56	72	64	62	54
Day 19	50	48	62	56	88	64	64	58

DAY20	16	35	20	75	35	56	72	34
DAY21	34	56	64	68	56	64	45	62
Day 22	56	34	18	58	64	78	56	42
DAY23	46	28	64	56	67	58	18	34
DAY24	54	42	34	78	46	64	30	68
Day 25	40	80	55	44	88	80	34	64
DAY26	64	42	56	64	52	46	58	56
DAY27	68	45	32	38	56	80	56	58
DAY28	88	36	58	34	24	74	62	61

Values are expressed as the mean ± S.D

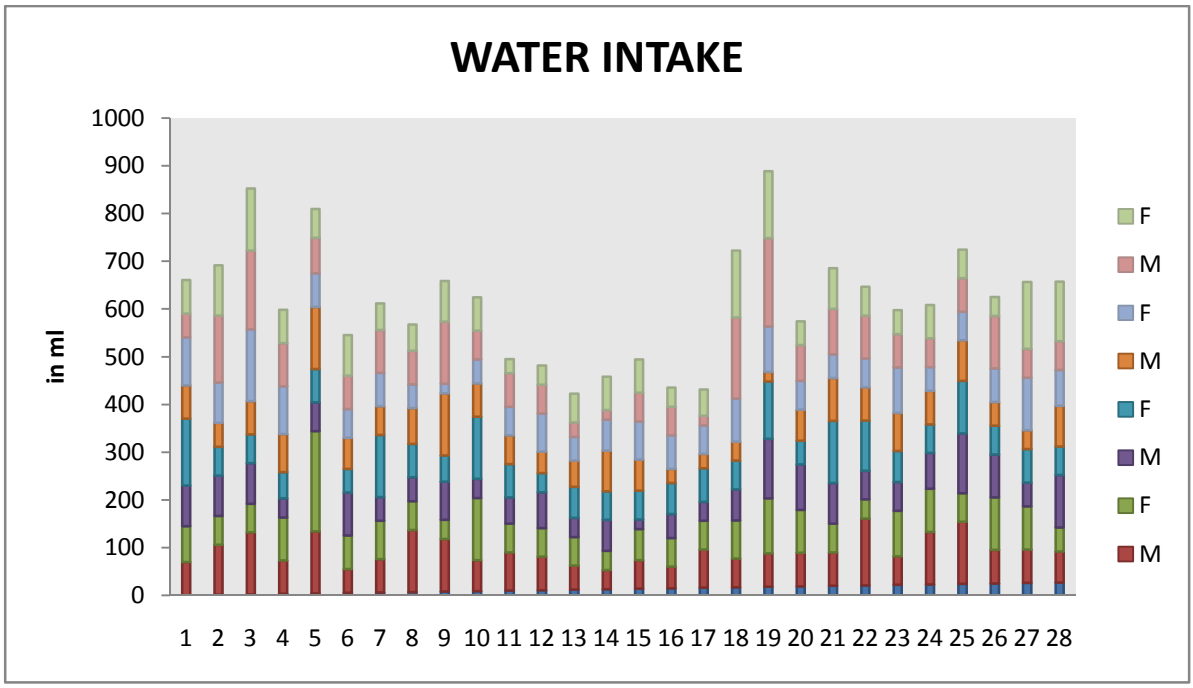


EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF KUSTATHI CHOORNAM WITH HOT WATER ON WATER INTAKE IN ml

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	70	75	85	140	70	100	50	70
DAY2	105	60	85	60	50	85	140	105
DAY3	130	60	85	60	70	150	165	130
Day 4	70	90	40	55	80	100	90	70
DAY5	130	210	60	70	130	70	75	60
Day 6	50	70	90	50	65	60	70	85
DAY7	70	80	50	130	60	70	90	55
DAY8	130	60	50	70	75	50	70	55
Day 9	110	40	80	55	130	20	130	85
DAY10	65	130	40	130	70	50	60	70
Day 11	80	60	55	70	60	60	70	30
DAY12	70	60	75	40	45	80	60	40
DAY13	50	60	40	65	55	50	30	60
Day 14	40	40	65	60	85	65	20	70
DAY15	60	65	20	60	65	80	60	70
Day 16	45	60	50	65	30	70	60	40
DAY17	80	60	40	70	30	60	20	55
DAY18	60	80	65	60	40	90	170	140
Day 19	70	115	125	120	20	95	185	140

DAY20	70	90	95	50	65	60	75	50
DAY21	70	60	85	130	90	50	95	85
Day 22	140	40	60	105	70	60	90	60
DAY23	60	95	60	65	80	95	70	50
DAY24	110	90	75	60	70	50	60	70
Day 25	130	60	125	110	85	60	70	60
DAY26	70	110	90	60	50	70	110	40
DAY27	70	90	50	70	40	110	60	140
DAY28	65	50	110	60	85	75	60	125

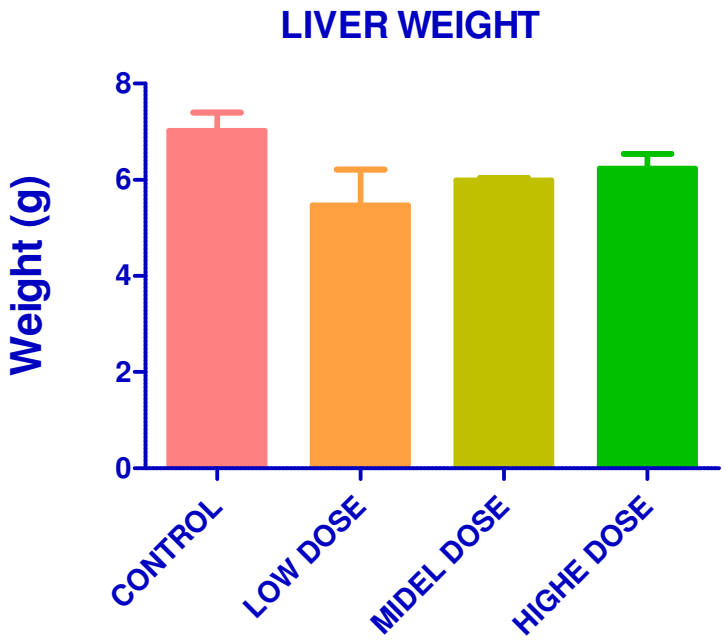
Values are expressed as the mean ± S.D

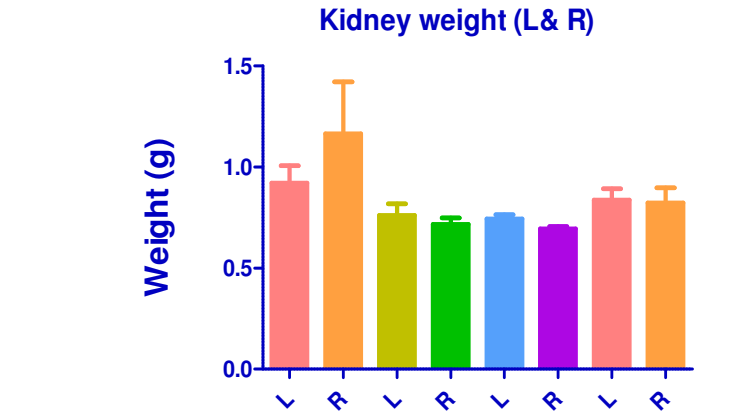


EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF KUSTATHI CHOORNAM WITH HOT WATER ON ORGAN WEIGHT in gm

GROUP		CONTROL	Low Dose	Middle Dose	High Dose
LIVER WEIGHT		7.015±0.3805	5.468±0.7463	5.987±0.0561	6.24±0.3043
KIDNEY WEIGHT	L	0.921±0.08582	0.7613±0.05674	0.7443±0.01975	0.8363±0.05655
	R	1.165±0.2567	0.717±0.03279	0.696±0.009074	0.8233±0.07304
HEART WEIGHT		0.8463±0.0393	0.8493±0.08815	0.7603±0.03398	0.972±0.1363
LUNGS WEIGHT		1.721±0.4071	0.8027±0.06003	1.016±0.2056	1.601±0.4463
TESTIS WEIGH		2.841±0.383	2.511±0.3985	2.101±0.3407	2.412±0.4074
UTERUS		0.4477±0.0465	0.463±0.04579	0.4347±0.04944	0.6013±0.1393

Values arae expressed as mean ± SEM Statistical significance (p) calculated by one way ANOVA followed by dunnett's (n=6); $^{ns}p>0.05$, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group.

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Weight (g)
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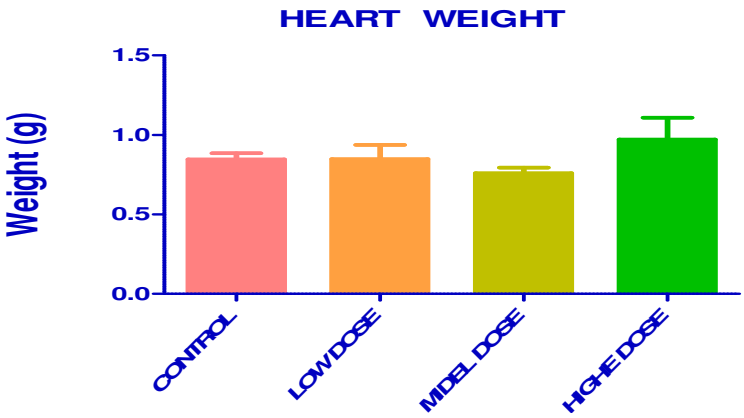
0.5
0.0
L
R
L
R
L
R
L
R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Weight (g)
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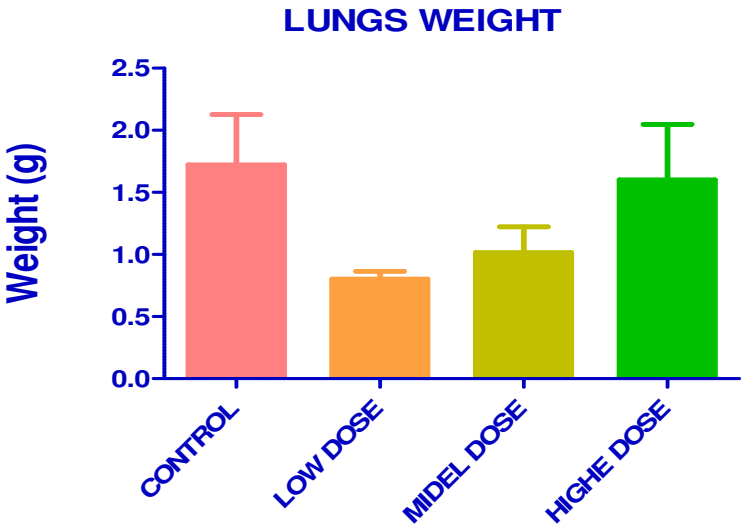
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE


LUNGS WEIGHT
Weight (g)
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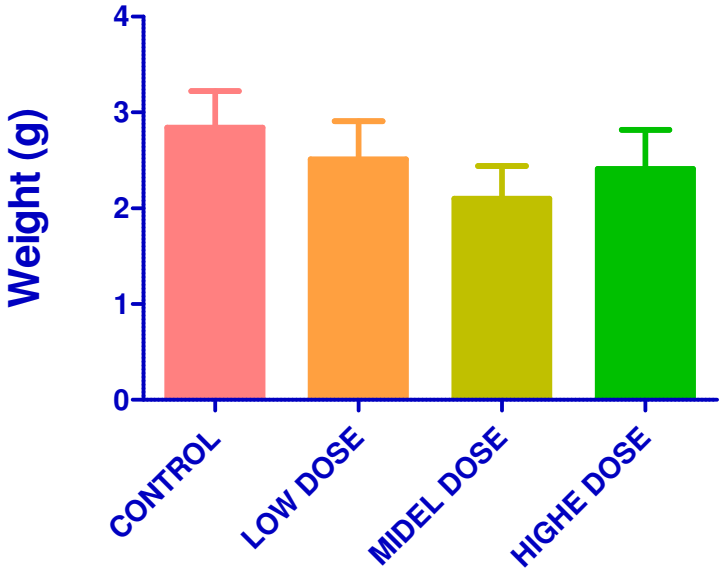
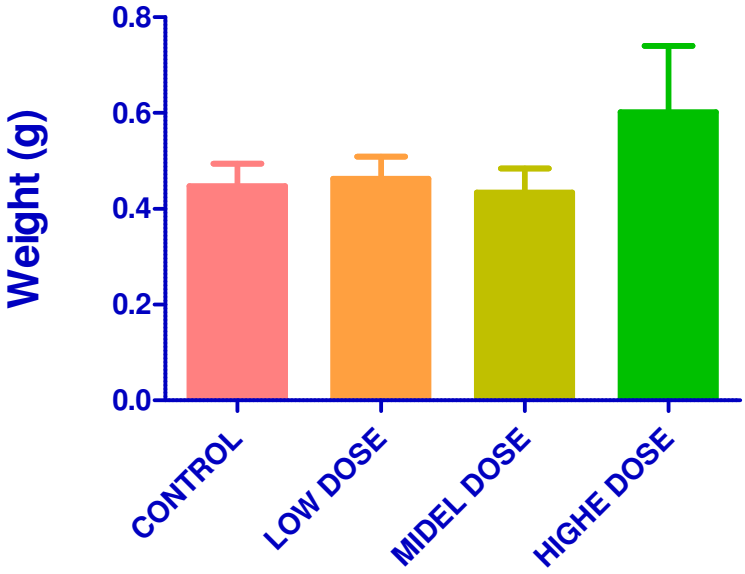
2.0
1.5
1.0
0.5
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE

TESTIS WEIGHT



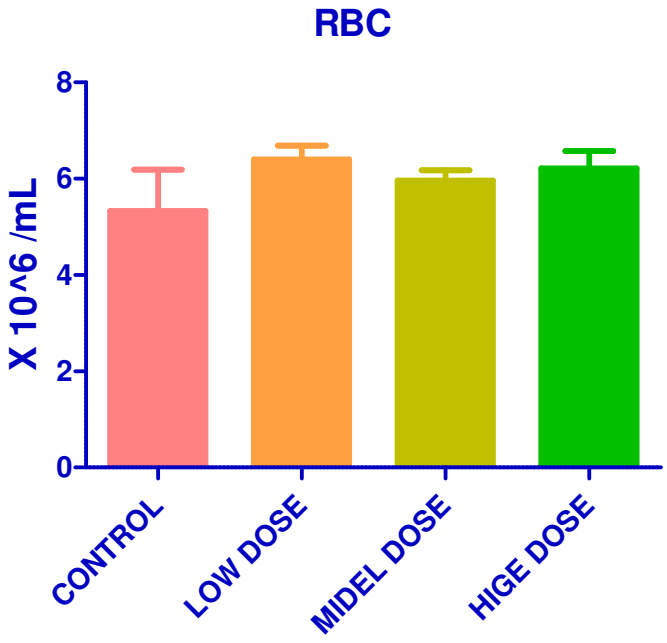
UTERUS

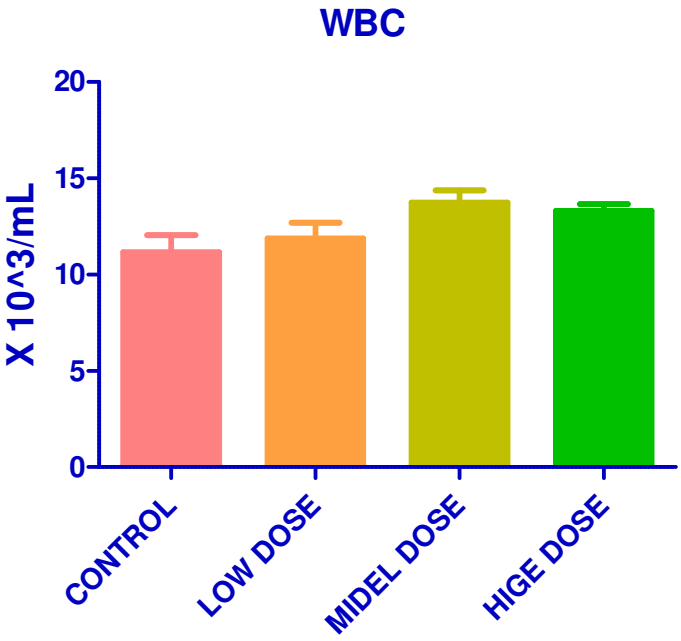


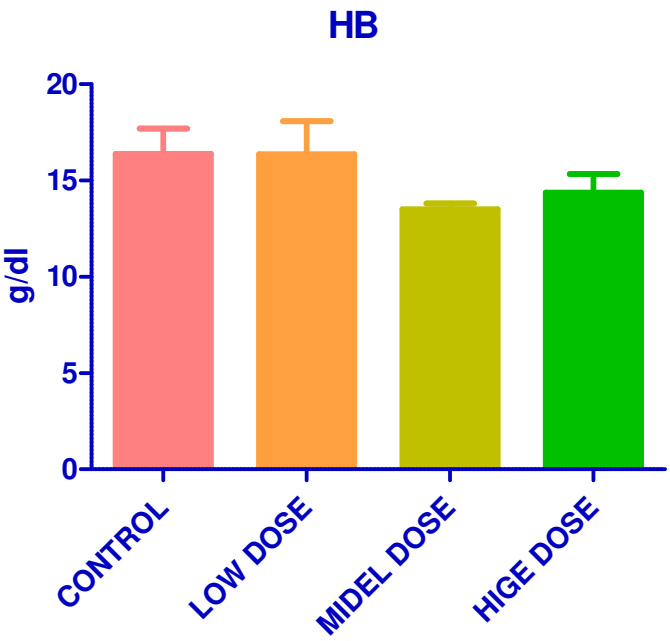
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F KUSTATHI CHOORNAM WITH HOT WATER ON HAEMATOLOGICAL PARAMETERS

Groups	Control	Low Dose	Middle Dose	High Dose
Rbc ($X10^3/\mu l$)	5.33±0.8585	6.403±0.289	5.96±0.2173	6.213±0.3619
Wbc($X10^6/\mu l$)	11.17±0.8762	11.87±0.8212	13.73±0.636	13.3±0.3606
Hb (g/dl)	16.4±1.29	16.37±1.707	13.5±0.3055	14.37±0.977

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



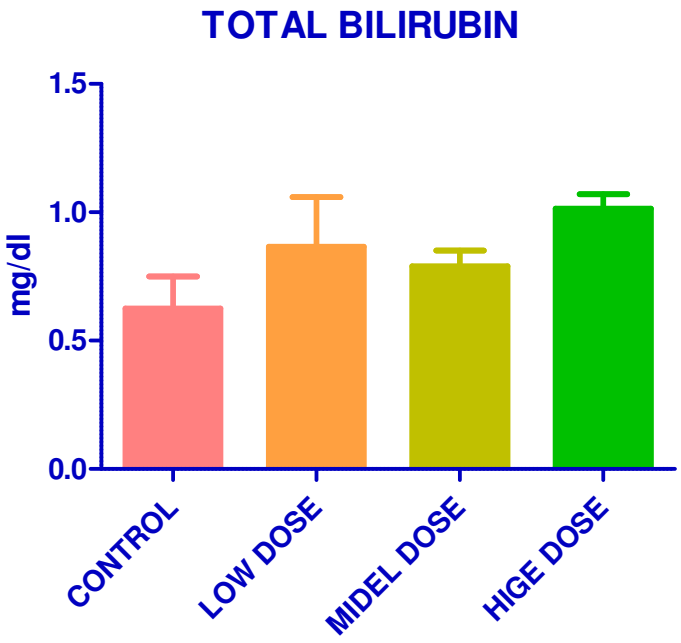

WBC
X 10^3/mL
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HB
g/dl
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

EFFECT OF SUB ACUTE DOSES (28 DAY) 0F KUSTATHI CHOORNAM WITH HOT WATER ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total Bilirubin(mg/dl)	0.625±0.125	0.865±0.195	0.79±0.06	1.015±0.055

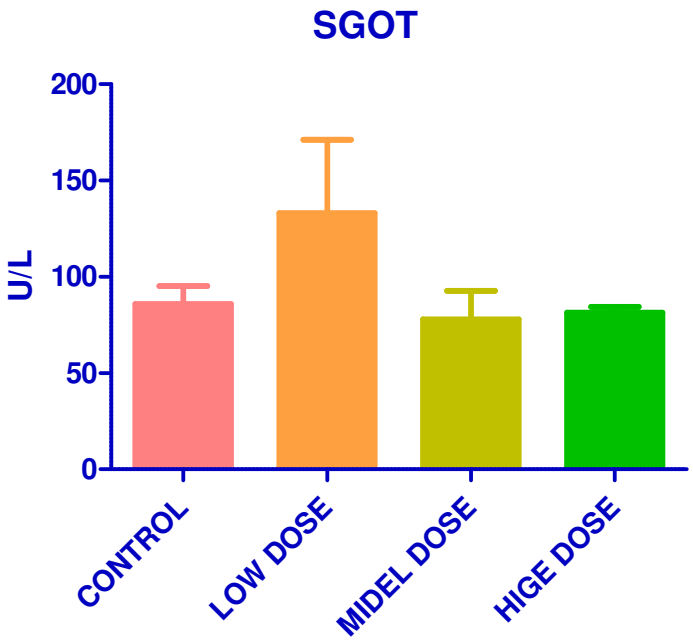
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.

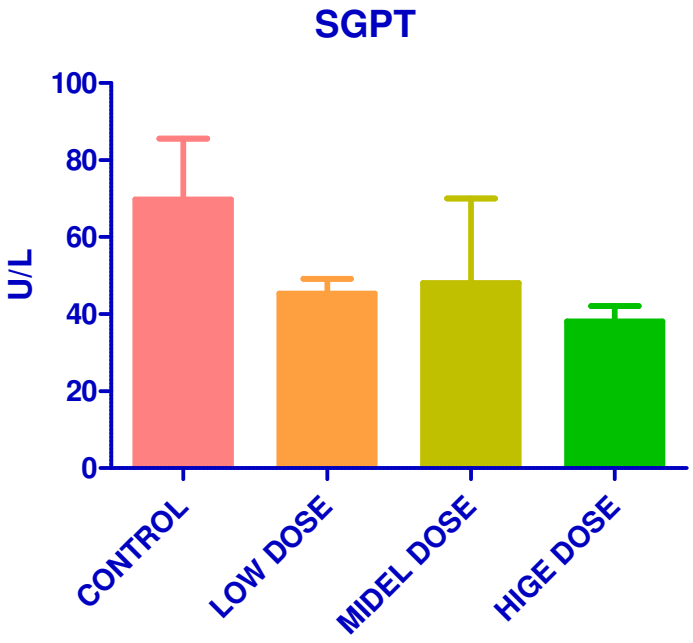


EFFECT OF SUB ACUTE DOSES (28 DAY) 0F KUSTATHI CHOORNAM WITH HOT WATER ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
SGOT (U/L)	85.95±9.25	133.2±37.95	77.9±14.9	81.35±3.05
SGPT (U/L)	69.79±15.72	45.4±3.8	48.15±21.85	38.15±3.95
ALP (U/L)	308.2±24.55	321.8±15.75	247.8±10.55	267.3±1.9

Values are expressed as the mean ± S.D; Statistical significance (p) calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.




SGPT
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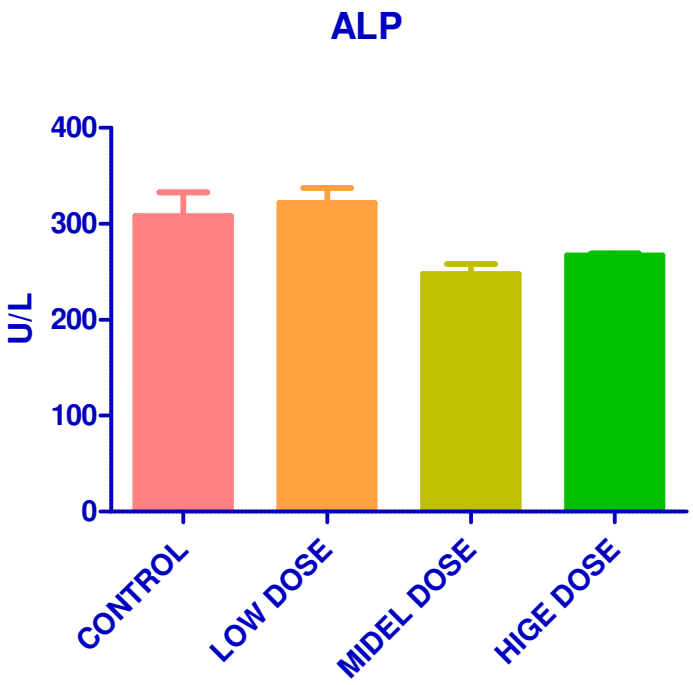
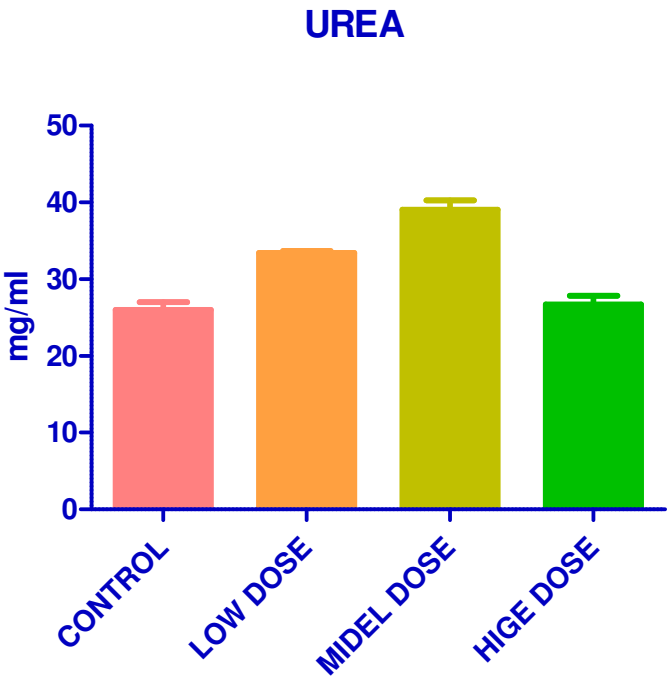
80
60
40
20
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


ALP
400
300
200
100
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

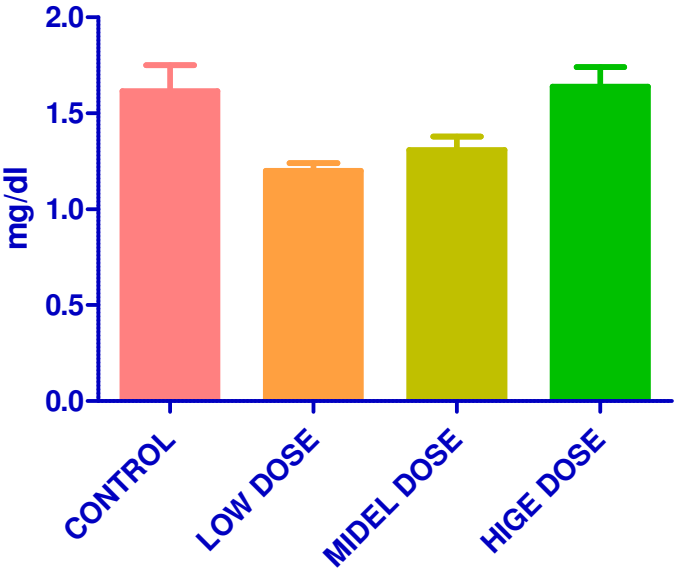
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F KUSTATHI CHOORNAM WITH HOT WATER ON BIOCHEMICAL PARAMETER (KIDNEY PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Urea (mg/dl)	26.03±1.01	33.45±0.25	39.08±1.18	26.74±1.13
Uric acid (mg/dl)	1.615±0.135	1.2±0.04	1.31±0.07	1.64±0.1
Creatinine (mg/dl)	0.33±0.05	0.275±0.005	0.23±0.02	0.29±0.09

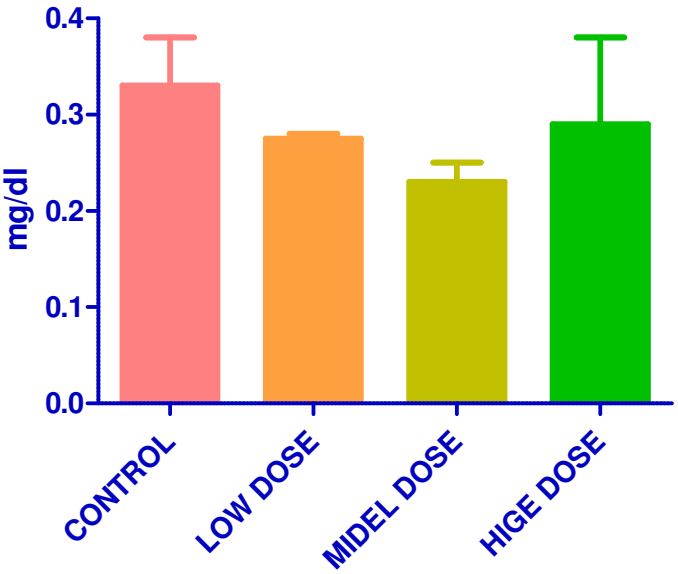
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



URIC ACID



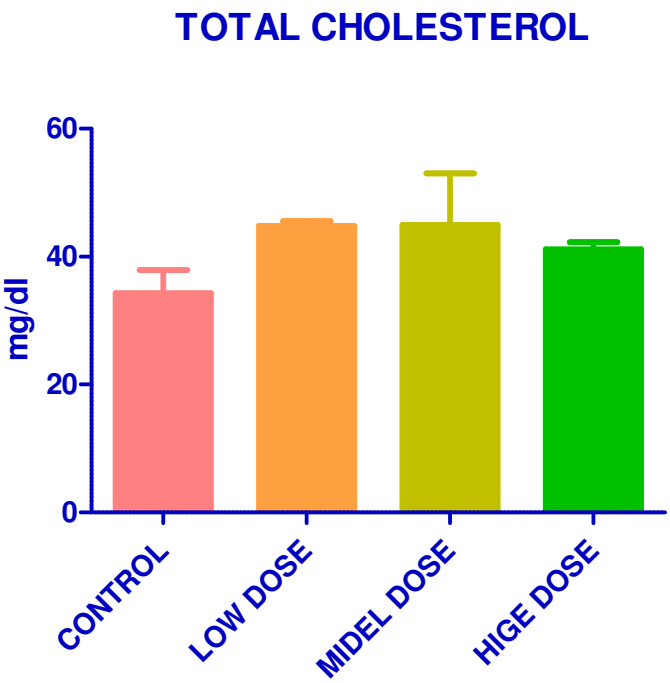
CREATININE

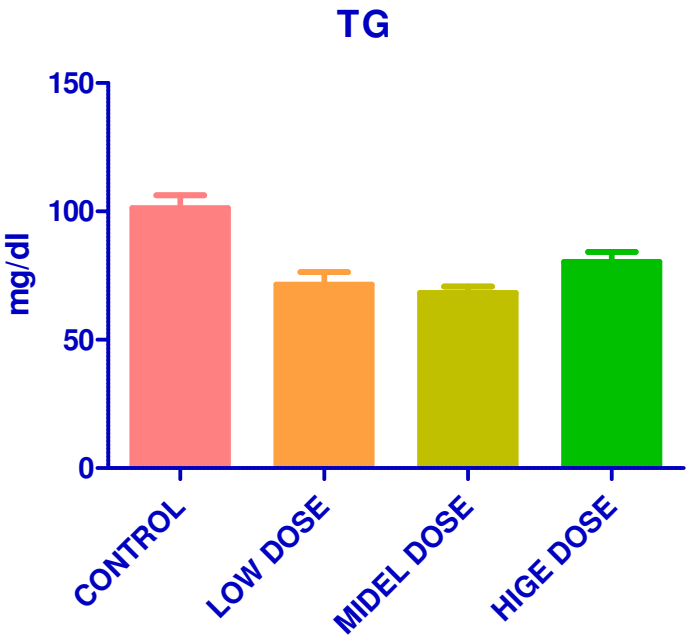


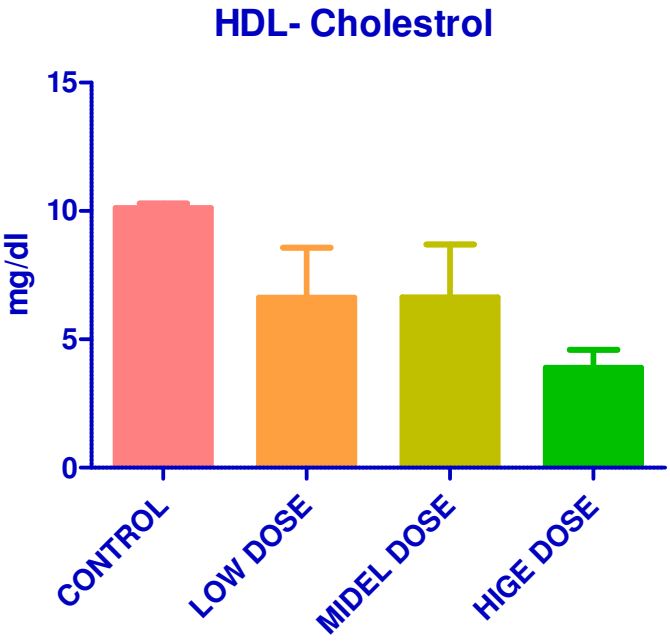
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F KUSTATHI CHOORNAM WITH HOT WATER ON BIOCHEMICAL PARAMETER (LIPID PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total cholesterol (mg/dl)	34.3±3.6	44.85±0.75	44.95±8.05	41.2±1.1
Triglycerides (mg/dl)	101.3±5	71.55±4.85	68.28±2.48	80.4±3.8
HDL-Cholesterol (mg/dl)	10.12±0.185	6.625±1.945	6.65±2.05	3.9±0.7

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.







RESULTS:

CLINICAL SIGNS:

All animals in this study were free of toxic clinical signs throughout the dosing period of 28 days.

Mortality:

All animals in control and in all the treated dose groups survived throughout the dosing period of 28 days.

Body weight:

Results of body weight determination of animals Table-1 from control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days.

Food consumption:

During dosing and the post-dosing recovery period, the quantity of food consumed by animals from different dose groups was found to be comparable with that by control animals.

Organ Weight:

Group Mean Relative Organ Weights (% of body weight) are recorded in Table No.4 Comparison of organ weights of treated animals with respective control animals on day 29 was found to be comparable similarly.

Hematological investigations:

The results of hematological investigations (Table 4) conducted on day 29 revealed following significant changes in the values of different parameters investigated when compared with those of respective controls; however, the increase or decrease in the values obtained was within normal biological and laboratory limits or the effect was not dose dependent.

Biochemical Investigations:

Results of Biochemical investigations conducted on days 29 and recorded in Table 2 revealed the following significant changes in the values of hepatic serum enzymes studied. When compared with those of respective control. However, the increase or decrease in the values obtained was within normal biological and laboratory limits.

Histopathology:

In histopathological examination, revealed normal architecture in comparison with control and treated animal.

DISCUSSION:

1) All the animals from control and all the treated dose groups up to 500 mg/kg survived throughout the dosing period of 28 days.

2) No signs of toxicity were observed in animals from different dose groups during the dosing period of 28 days.

3) Animals from all the treated dose groups exhibited comparable body weight gain with that of controls throughout the dosing period of 28 days.

4) Food consumption of control and treated animals was found to be comparable throughout the dosing period of 28 days

5) Haematological analysis conducted at the end of the dosing period on day 29, revealed no abnormalities attributable to the treatment.

6) Biochemical analysis conducted at the end of the dosing period on day 29 no abnormalities attributable to the treatment.

7) Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable with that of respective controls.

8) Histopathological examination revealed normal architecture in comparison with control and treated animal.

SUMMARY AND CONCLUSION:

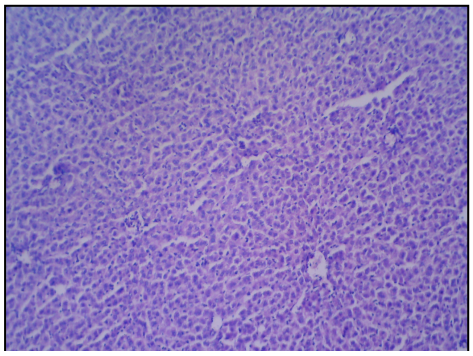
In conclusion **KUSTATHI CHOORNAM WITH HOT WATER** can be considered safe, as it did not cause either any lethality or adverse changes with general behavior of rats and also there were no observable detrimental effects (100 to 300 mg/kg body weight) over a period of 28 days. Our results have demonstrated that the **KUSTATHI CHOORNAM WITH HOT WATER** is relatively safe when administered orally in rats.

9.0 ABBRVIATION

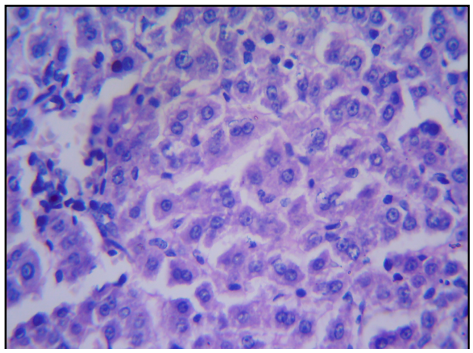
No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o.	peros
mL	Milliliter
%	percentage
R&D	Research and Development
EDTA	Ethylene Diamine Tetra Acetic Acid
M	Male
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level
MLD	Minimum Lethal Dose
MTD	Maximum Tolerated Dose
OECD	Organisation of Economic Co-operation and Development
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on

HISTOPATHOLOGY - TOXICITY STUDY

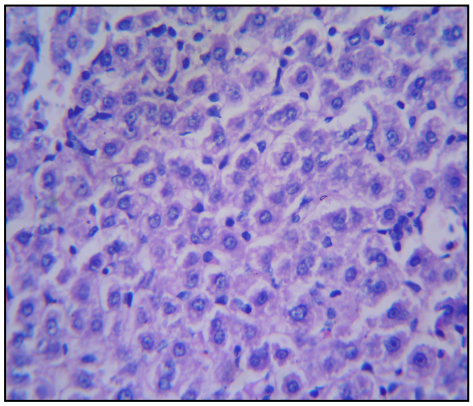
SPECIMEN : A) Liver. Group – : Kustathi choornam.



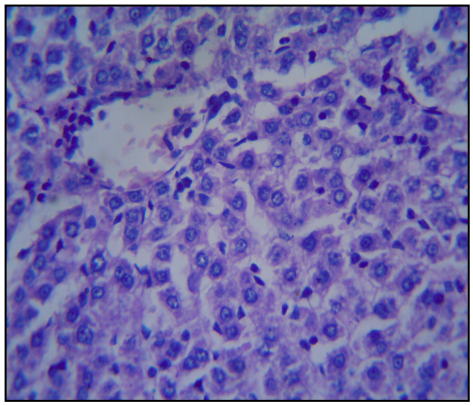
40x shows altere lobular architectuire



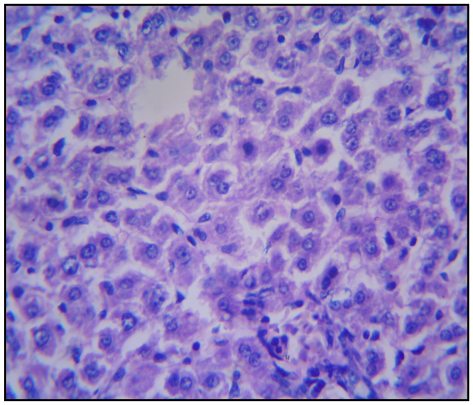
40x shows central vein dilatation and interface hepatitis



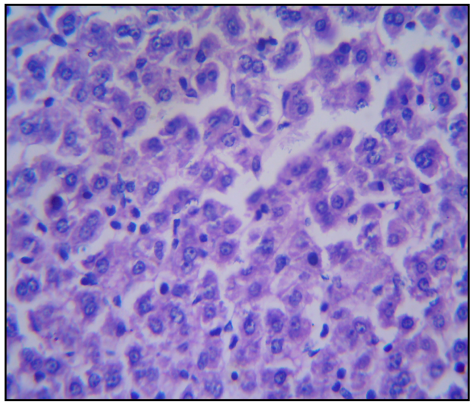
40x shows interface hepatitis



40x shows reactive atypia



40x shows altere lobular architectuire



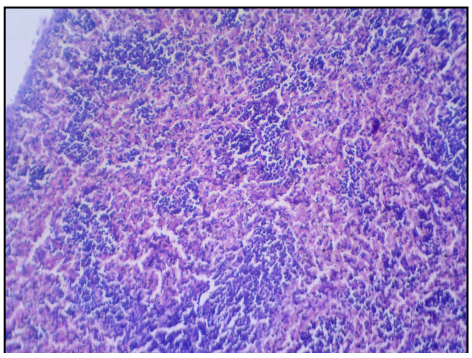
40x shows sinusoidal dilatation

MICROSCOPIC APPEARANCE:

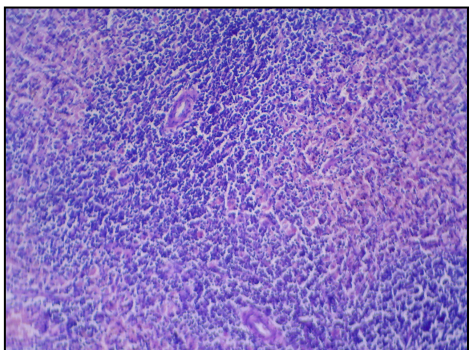
Section from liver shows lobular architecture with interface hepatitis. Individual Hepatocytes shows reactive atypia. Portal triad shows no significant pathology. Central vein and Sinusoids show dilatation.

SPECIMEN : B) spleen.

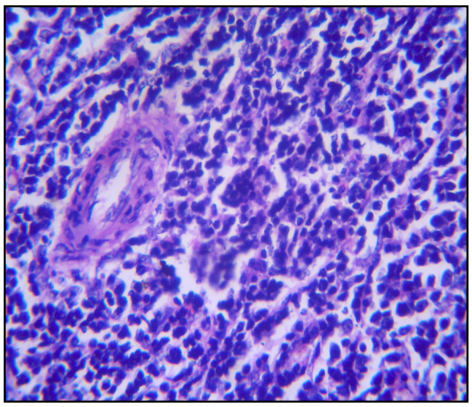
Group – : Kustathi choornam



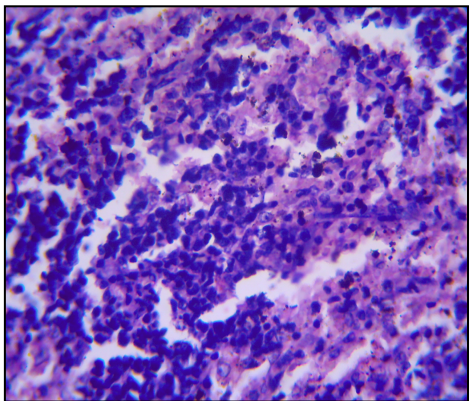
10x show snormal red and white pulp



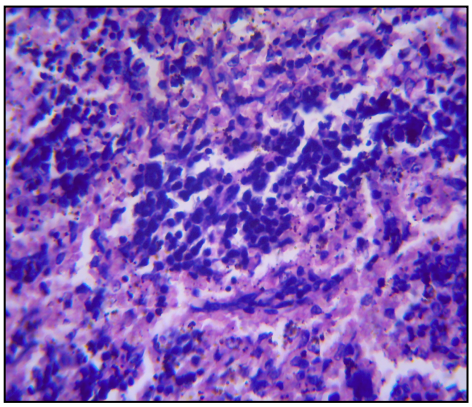
10x shows spleen



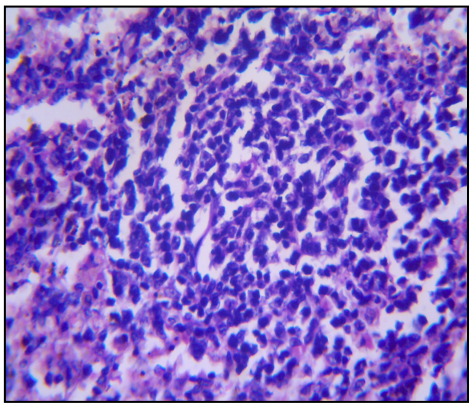
40x shows normal pencillar artery



40x shows pigment laden macrophages with lymphocytic infiltrates



40x shows red pulp shows pigment laden macrophages



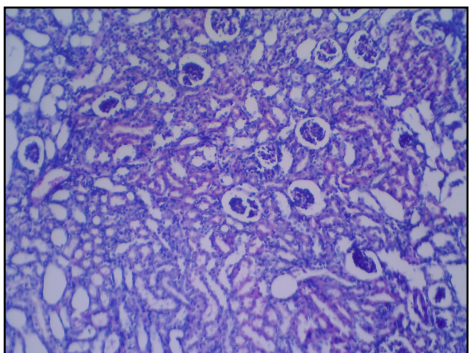
40x shows white pulp with lymphocytic infilatrates

MICROSCOPIC APPEARANCE:

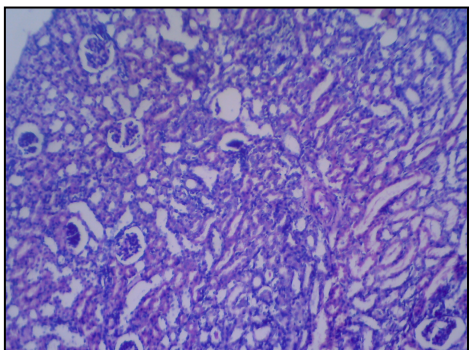
Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. Megakaryocytes

SPECIMEN : C) Kidney.

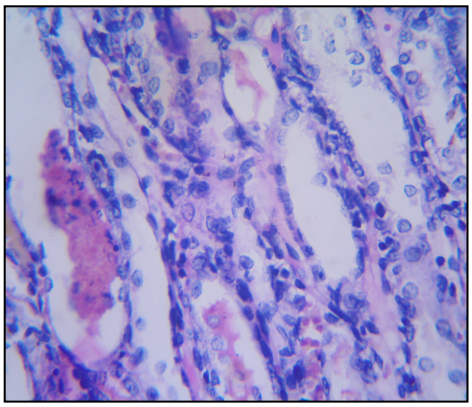
Group – : Kustathi choornam



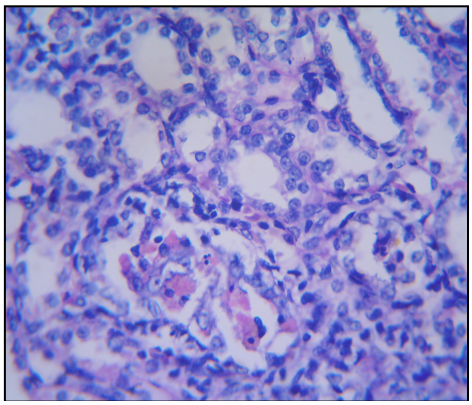
10x show snormal cortex and medulla



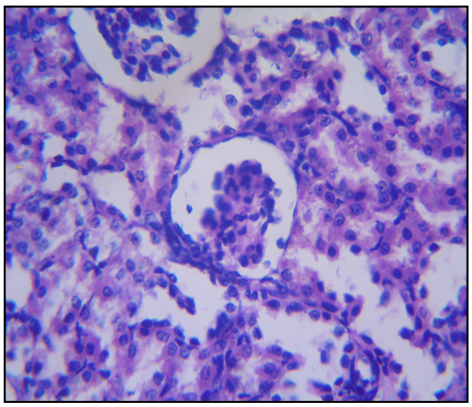
10x shows cortex



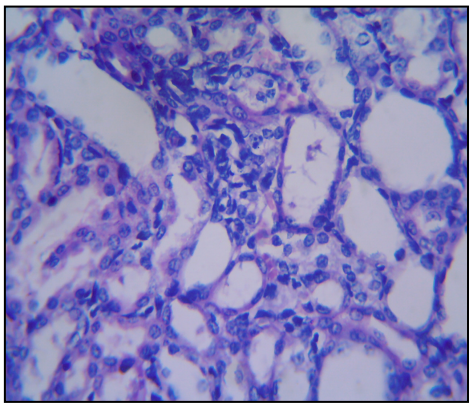
40x shows blood vessels congestion



40x shows interstitium



40x shows normal glomeruli



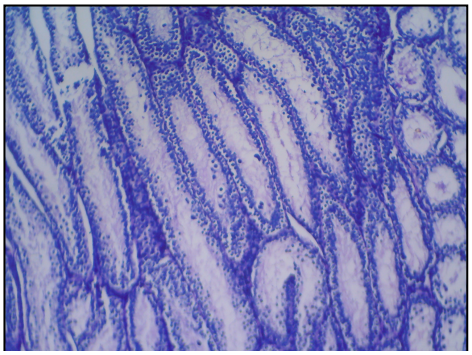
40x shows normal tubules

MICROSCOPIC APPEARANCE:

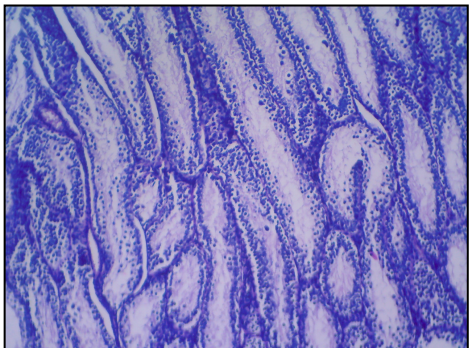
Section from kidney shows both cortex and medulla. Glomeruli and tubules shows no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion. There is no evidence of toxic changes.

SPECIMEN : D) Testis

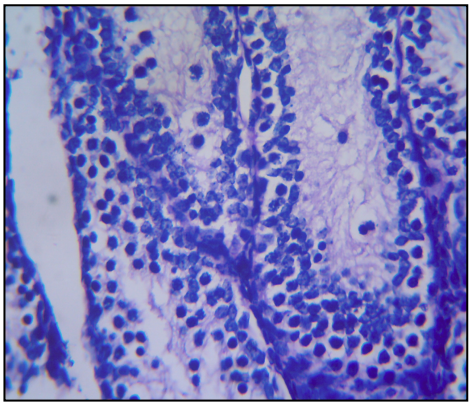
Group – : Kustathi choornam



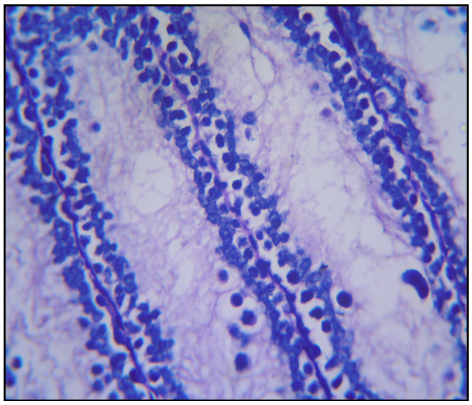
10x shows focal maturation arrest



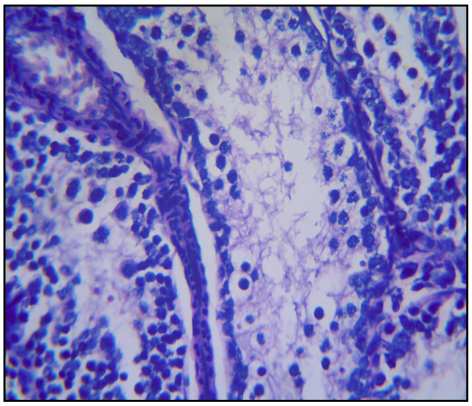
10x shows normal tubules with maturation arrest



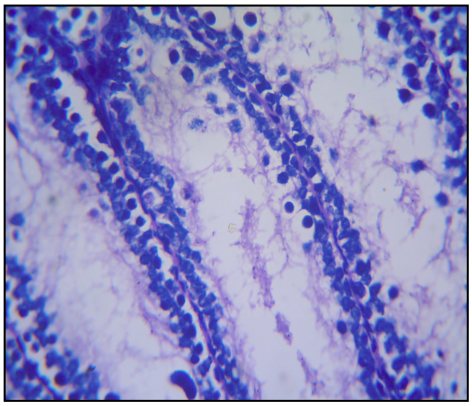
40x shows normal spermatogenesis with maturation arrest



40x shows spermatogenesis (2)



40x shows spermatogenesis



40x shows tubules

MICROSCOPIC APPEARANCE:

Section from testes with seminiferous tubules showing maturation arrest with lacking of spermatogenesis.

ANNEXURE – IV

ASSESSMENT FORMS

FORM I – SCREENING FORM

FORM II - CONSENT FORM

FORM III – CASE SHEET PROFORMA

FORM IV - LABORATORY INVESTIGATIONS

FORM V – CLINICAL ASSESSMENT

FORM VI - PATIENT WITHDRAWAL FORM

FORM VII - DRUG COMPLIANCE FORM

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL PALAYAMKOTTAI.

POST GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM.

AN OPEN CLINICAL TRIAL ON KUSTATHI CHOORNAM AND ERANDA THYLAM FOR THE TREATMENT OF 'THANDAGAVADHAM'.

FORM I –SCREENING FORM

1. OP/ IP No:	2. BED No:	3. Sl. No:
4. NAME:	5. AGE:	6. GENDER:
7. OCCUPATION:	8. SOCIAL STATUS	
9. DATE OF ADMISSION:	10. DATE OF DISCHARGE:	
11. POSTAL ADDRESS:		

INCLUSION CRITERIA:

- Age : 20-60 yrs
- Sex : Both male and female
- Patients having symptoms of Pain in the lumbar region, Radiating pain to buttocks and lower limbs ,stiffness present in lumbar region, Exacerbation of pain on movements, Pain increased on forward bending, Tingling sensation.(Numbness)
- Patients who are willing to give radiological investigation and provide blood for lab investigation.
- Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48 days but can option out of the trial of his/her own conscious discretion.

EXCLUSION CRITERIA:

- Cardiac disease
- Auto immune diseases like Rheumatoid arthiritis, SLE, Psoriasis, Mixed connective tissue disorder.

- Spina bifida
- Liver Disease
- Pregnancy and lactation
- Osteo myelitis
- Renal Disease
- Tuberculosis in spine
- Patient with any other serious illness
- Other systemic illness
- Dislocation

WITHDRAWAL CRITERIA

Intolerance to the drug &development of adverse reactions during drug trial.

- Poor patient compliance & defaulters.
- Patient turned unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness

GOVERNMEN SIDDHA MEDICAL COLLEGE & HOSPITAL, PALAYAMKOTTAI.

POST GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL ON KUSTATHI CHOORNAM AND ERANDA THYLAM' FOR THE TREATMENT OF 'THANDAGAVADHAM'

Form: II CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the patient.

Signature…….

Date…… Name……

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial of **KUSTATHI CHOORNAM (INTERNAL) AND ERANDA THYLAM (EXTERNAL)** for the treatment of THANDAGAVATHAM.

Signature……

Name……..

Date……..

அரசினர் சித்த மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை பாளையங்கோட்டை

பட்டமேற்படிப்பு சிறப்புமருத்துவத்துறை.

குஷ்டாதி சூரணம் மற்றும் ஏரண்ட தைலம் இவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு.

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் ஒப்புதல்:

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறையைப் பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும் அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு தண்டகவாதம் என்னும் நோய்க்கான **குஷ்டாதி சூரணம் மற்றும் ஏரண்ட தைலம்** இவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:
கையொப்பம்:

இடம்:
பெயர்:

தேதி:
சாட்சிக்காரர் கையொப்பம்:

இடம்:
பெயர்

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CASE PROFORMA

Dissertation done by :

I.P. No :		Occupation	:
Bed No	:	Income	:
Ward	:	Nationality	:
Name	:	Religion	:
Age	:	Date of Admission	:
Sex	:	Date of Discharge	:
Permanent Address :		Diagnosis	:
		Result	:
		Medical Officer	:

Complaints and duration:

History of present illness:

History of Previous Illness:

Personal History including habits:

Family History:

GENERAL CONDITIONS ON EXAMINATION

1. Consciousness :
2. General appearance :
3. Stature :
4. Nourishment :

5. Skin Changes :

6. Face :

7. Pallor :

8. Jaundice :

9. Cyanosis :

10. Clubbing :

11. Lymphadenopathy :

12. Abdominal Distension :

13. Jugular Venous Pulsation :

14. Engorged veins :

15. Koilonychia :

16. Pedal oedema :

17. Generalised Oedema :

18. Temperature :

19. Pulse : Rate : /min

Rhythm :

Volume :

Character :

Peripheral Pulses :

Pulses paradoxus :

20. Respiratory Rate : /min

21. Heart Rate : /min

22. Blood pressure : (mm/Hg)

Right Left Upper limb

23. Miscellaneous

சித்த முறை தேர்வு

1. நிலம்

    குறிஞ்சி

    முல்லை

    மருதம்

    நெய்தல்

    பாலை

2. பருவ காலம்

    கார் காலம் (ஆவணி - புரட்டாசி)

    கூதிர் காலம் (ஐப்பசி - கார்த்திகை)

    முன்பனி (மார்கழி - தை

    பின்பனி (மாசி - பங்குனி)

    இளவேனில் (சித்திரை - வைகாசி)

    முதுவேனில் (ஆனி - ஆடி)

3. யாக்கை (உடல்)

    வாதம்

    பித்தம்

    கபம்

    கலப்பு

4. குணம்

    சத்துவம்

    இராசதம்

    தாமசம்

5. பிற உறுப்புகளின் நிலை

    இருதயம் -

    புப்புசம் -

    இரைப்பை -

    கல்லீரல் -

    மண்ணீரல் -

    சிறுகுடல் -

பெருங்குடல் -

சிறுநீரகம் -

மூளை -

கருப்பை -

6. உயிர் தாதுக்கள்

(அ) வாதம் -

பிராணன் -

அபானன் -

வியானன் -

உதானன் -

சமானன் -

நாகன் -

கூர்மன் -

கிருகரன் -

தேவதத்தன் -

தனஞ்செயன் -

(ஆ) பித்தம்

அனற் பித்தம் -

இரஞ்சக பித்தம் -

சாதக பித்தம் -

ஆலோசக பித்தம் -

பிராசக பித்தம் -

(இ) கபம்

அவலம்பகம் -

கிலேதகம் -

போதகம் -

தற்பகம் -

சந்திகம் -

7. உடல் தாதுக்கள்

சாரம் -

செந்நீர் -

ஊண் -

கொழுப்பு -

என்பு -

மூளை -

சுக்கிலம்.˙.சுரோணிதம் -

8. எண் வகைத்தேர்வுகள்

நாடி -

ஸ்பரிசம் -

நா -

நிறம் -

மொழி -

விழி -

மலம்

நிறம் -

எடை -

இறுகல் -

இளகல் -

சிறுநீர்

1 நீர்க்குறி

நிறம் -

மணம் -

எடை -

நுரை -

எஞ்சல் -

2. நெய்க்குறி

EXAMINATION OF THE SPINE AND JOINTS

A) GALS LOCOMOTOR SCREENING

A(Appearance) M (Movement)

G

A

L

S

B) PROVOCATIVE TESTS

i. Straight leg raising test (SLR)
ii. Contralateral well leg raising test
iii. Braggard's test
iv. Femoral nerve stretch test
v. Schobler's test
vi. Forward bending to touch the toes
vii. Flip test
viii. Lassegue test
ix. Bowstring sign

C) INSPECTION

Skin over the vertebrae

Attitute and Defornity

Muscular Wasting
Trophic changes
Swelling
Fasciculation
Gait

D) PALPATION

Local temperature
Tenderness
Rigidity and Deformity
Wasting
Swelling
Lymphadenopathy
Cold abscess

E) GENERAL MOVEMENTS

Painful / Not painful
Pain scale used: Back pain functioning scale.
Restricted / Non restricted - **Restricted movement assessment scale**
Excess Mobility in any direction. Present/ Not present

Examination of CVS
Examination of RS
Examination of Abdomen
Case Summary:
Differential Diagnosis:
Diagnosis:
Follow Up
Date
Symptoms
Drug

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Form IV -LABORATORY INVESTIGATIONS

1. OP/ IP No: 2. BED No: 3. Sl. No:
4. NAME: 5. AGE: 6. GENDER:
7. OCCUPATION: 8. SOCIAL STATUS
9. DATE OF ENROLLMENT: 10. DATE OF DISCHARGE:
11. POSTAL ADDRESS:

Lecturer **HOD**

Date:

LABORATORY INVESTIGATION

1. BLOOD

TC : Cells / cu.mm

DC : P % L% E % M %

ESR :

1/2 hour : mm

1 hour : mm

Hb :

Blood Sugar :

Blood Urea :

Serum Cholesterol :

2. URINE

Albumin :

Sugar :

Deposits :

3. Motion

Ova :

Cyst :

5. RADIOGRAPHIC FINDINGS

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FORM - V ASSESSMENT PROFORMA

1. IP / OP No ..... 2. Sl. No .....

4. Name. . . . . .

5. Date of admission | | | | | | |

6. Date of discharge | | | | | | |

CLINICAL ASSESSMENT:

Sl.no	Signs and symptoms	10th day	20th day	30th day
1.	Low back ache			
2.	Radiating pain to lower limbs			
3.	Restricted movements			
4.	Tenderness			
5.	Numbness in lower limbs			

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FORM - VI PATIENT WITHDRAWAL FORM

1. OP / IP No ..... 2. S.No. .....3.Date: _____

4. Name ..... 5. Age _____ 6. Gender _____

7. Postal address:

Complaints and Duration:

Irregular Treatment:

Adverse Reactions:

Other causes:

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FORM VII - DRUG COMPLIANCE FORM

Name of the Drug:**KUSTATHI CHOORNAM**

Drugs issued: ……grams **Drugs returned**: ……grams

S.NO	**DATE**	MORNING/TIME	NIGHT/TIME
Day 1			
Day 2			
Day 3			
Day 4			
..			
..			
Up to day 30			

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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